

Subject Case Report Forms

1057 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 11:58:42

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Form: Subject**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:15**

**Generated On: 20 Jul 2016 11:58:42**

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Screening number	1057
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Subject Status**

**Form: Subject Status**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:15**

**Generated On: 20 Jul 2016 11:58:42**

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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

30 JAN 2014  
DD/MMM/YYYY

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Randomization Time

14:03  
hour:min 24-hour clock

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

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Date of Visit

13 JAN 2014  
DD/MMM/YYYY

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Additional Informed Consent**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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

Yes ☒

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Consent Date

13 JAN 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 ☒

---

Consent Date

13 JAN 2014  
DD/MMM/YYYY

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Inclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Inclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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Inclusion Criterion Number	1
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Inclusion Criterion	Subject has signed the ICF and is able to understand the information provided in the Subject Information 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: 1057**

**Folder: Screening**

**Form: Inclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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Inclusion Criterion Number	2
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Inclusion Criterion	Subject is at a minimum 22 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: 1057**

**Folder: Screening**

**Form: Inclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Inclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Inclusion Criteria (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Inclusion Criteria (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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Inclusion Criterion Number	6
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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 ).
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

\*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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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 ≥35 kg/m2.
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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Exclusion Criterion Number	13
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Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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"/>
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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Exclusion Criterion Number	16
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Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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"/>
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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.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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).
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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Exclusion Criterion Number	19
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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).
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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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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.	<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.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Exclusion Criteria (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

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Exclusion Criterion Number	22
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Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
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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: 1057**

**Folder: Screening**

**Form: Demographics**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:15**

**Generated On: 20 Jul 2016 11:58:42**

Date of Birth	(b) (6)
Sex	Female
Race	White
Other, specify	
Ethnicity	Not Hispanic
Date the Subject signed the Informed Consent	13 JAN 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	11:31 hour:min 24-hour clock
Age(Derived)	50

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection

13 JAN 2014  
DD/MMM/YYYY

---

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
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---

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
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Number	1
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Diagnosis Description	PRESBYOPIA
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Onset Date DD/MMM/YYYY	UN UNK 2012
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Stop Date DD/MMM/YYYY	
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Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
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---

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

Number	2
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---

Diagnosis Description	LASIK SURGERY BOTH EYES
-----------------------	-------------------------

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Onset Date DD/MMM/YYYY	UN UNK 2002
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Stop Date DD/MMM/YYYY	UN UNK 2002
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
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Number	3
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Diagnosis Description	WISDOM TEETH EXTRACTIONS TIMES 4
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Onset Date DD/MMM/YYYY	UN UNK 1981
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Stop Date DD/MMM/YYYY	UN UNK 1981
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---

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
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Number	4
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Diagnosis Description	MILK DUCTS REMOVED, LEFT BREAST
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Onset Date DD/MMM/YYYY	UN UNK 1997
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Stop Date DD/MMM/YYYY	UN UNK 1997
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---

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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Date of collection	13 JAN 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

---

Number	5
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---

Diagnosis Description	PNEUMONIA, HOSPITALIZED
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Onset Date DD/MMM/YYYY	UN UNK 1981
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Stop Date DD/MMM/YYYY	UN UNK 1981
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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Date of collection	13 JAN 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
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Number	6
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Diagnosis Description	HIGH CHOLESTEROL
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---

Onset Date DD/MMM/YYYY	UN UNK 2011
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---

Stop Date DD/MMM/YYYY	
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---

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

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Date of collection	13 JAN 2014 DD/MMM/YYYY
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---

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
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Number	7
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Diagnosis Description	HEMORRHAGE AFTER INJURY
-----------------------	-------------------------

---

Onset Date DD/MMM/YYYY	UN UNK 1983
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Stop Date DD/MMM/YYYY	UN UNK 1983
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

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

---

Number	8
--------	---

---

Diagnosis Description	C-SECTION
-----------------------	-----------

---

Onset Date DD/MMM/YYYY	(b) (6)
---------------------------	---------

---

Stop Date DD/MMM/YYYY	(b) (6)
--------------------------	---------

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

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

---

Number	9
--------	---

---

Diagnosis Description	CARPAL TUNNAL SYNDROME REPAIR, RIGHT WRISTS
-----------------------	--

---

Onset Date DD/MMM/YYYY	UN AUG 2012
---------------------------	-------------

---

Stop Date DD/MMM/YYYY	UN AUG 2012
--------------------------	-------------

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

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

---

Number	10
--------	----

---

Diagnosis Description	MYOPIA
-----------------------	--------

---

Onset Date DD/MMM/YYYY	UN UNK 2012
---------------------------	-------------

---

Stop Date DD/MMM/YYYY	UN UNK 2012
--------------------------	-------------

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

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

---

Number	11
--------	----

---

Diagnosis Description	CARPAL TUNNAL REPAIR, LEFT WRISTS
-----------------------	--------------------------------------

---

Onset Date DD/MMM/YYYY	UN OCT 2012
---------------------------	-------------

---

Stop Date DD/MMM/YYYY	UN OCT 2012
--------------------------	-------------

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of collection	13 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

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

---

Number	12
--------	----

---

Diagnosis Description	HYSTERECTOMY
-----------------------	--------------

---

Onset Date DD/MMM/YYYY	UN UNK 1983
---------------------------	-------------

---

Stop Date DD/MMM/YYYY	UN UNK 1983
--------------------------	-------------

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Were Vitals Signs assessed?

Yes ☒

---

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

---

Has the subject smoked within 15 minutes prior to  
assessment

No ☒

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

Time of assessment

12:47  
hour:min 24-hour clock

---

Pulse rate

68  
beats per minute

---

Respiratory rate

12  
breaths per minute

---

Blood Pressure (systolic)

112  
mmHg

---

Blood Pressure (diastolic)

68  
mmHg

---

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System General Appearance ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

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

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Thyroid Gland ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Heart ☒

---

Outcome

Normal ☒

---

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

---

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

---

Not Done

False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Chest ☒

---

Outcome

Normal ☒

---

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

---

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

---

Not Done

False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Lungs ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Gastrointestinal ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Cardiovascular System ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Neurologic ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Skin ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Back ☒

---

Outcome

Normal ☒

---

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

---

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

---

Not Done

False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Musculoskeletal ☒

---

Outcome

Normal ☒

---

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

---

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

---

Not Done

False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Abdomen ☒

---

Outcome

Normal ☒

---

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

---

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

---

Not Done

False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

System Dentition ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:19**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Has the subject received advices on the risks of  
smoking?

Yes ☒

---

Has a debriefing been performed about THS 2.2?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Identification of Current Cigarette Brand**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Date

13 JAN 2014  
DD/MMM/YYYY

---

Brand name

NATIVE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: THS 2.2 menthol product demonstration**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Has the subject seen a THS 2.2 menthol product  
demonstration?

Yes ☒

---

If the subject did not see the demonstration please  
explain

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Smoking History**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Assessment

13 JAN 2014  
DD/MMM/YYYY

---

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

No ☐

---

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

Yes ☐

---

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

>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: 1057**

**Folder: Screening**

**Form: Weight and Height**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Measurement(s) assessed?

Yes ☒

---

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

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

Weight

69.0  
kg

---

Height

151  
cm

---

BMI (Derived)

30.3  
kg/m2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the ECG performed? Yes ☒

---

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

---

---

Date of assessment: 13 JAN 2014  
DD/MMM/YYYY

---

---

Position Supine ☒

---

---

Heart Rate 58  
beats per minute

---

---

QRS Interval 86  
msec

---

---

QT Interval 417  
msec

---

---

QTcB Interval 412  
msec

---

---

QTcF Interval 414  
msec

---

---

PR Interval 144  
msec

---

---

Interpretation Normal ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:16**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Spirometry (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:20**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the spirometry performed? Yes ☒

---

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

---

Category Without short-acting ☒  
bronchodilator

---

Position SITTING

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 13:30

---

Predicted FVC value 3.00  
L

---

Best measured FVC value 2.56  
L

---

Percent of predicted FVC value 85  
%

---

Best measured FEV1 value 2.04  
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Spirometry (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:20**

**Generated On: 20 Jul 2016 11:58:42**

---

Predicted FEV1 value	2.39 L
----------------------	-----------

---

Percent of predicted FEV1 value	85 %
---------------------------------	---------

---

Calculated ratio between FEV1/FVC	0.80
-----------------------------------	------

---

MEF 25/75 value	2.21 L/s
-----------------	-------------

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Screening**

**Form: Spirometry (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:20**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the spirometry performed? Yes ☒

---

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

---

Category With short-acting bronchodilator ☒

---

Position SITTING

---

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

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 13:57

---

Name of bronchodilator ALBUTEROL SULFATE

---

Dose 180 MCG

---

Predicted FVC value 3.00  
L

---

Best measured FVC value 2.78  
L

---

Percent of predicted FVC value 86  
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Spirometry (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:20**

**Generated On: 20 Jul 2016 11:58:42**

---

Best measured FEV1 value	2.06 L
--------------------------	-----------

---

Predicted FEV1 value	2.39 L
----------------------	-----------

---

Percent of predicted FEV1 value	86 %
---------------------------------	---------

---

Calculated ratio between FEV1/FVC	0.74
-----------------------------------	------

---

MEF 25/75 value	1.51 L/s
-----------------	-------------

---

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

---

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

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Chest X-Ray**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

Yes ☒

---

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

---

Date of assessment

20 JAN 2014  
DD/MMM/YYYY

---

System

Chest ☒

---

Interpretation

Normal ☒

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Haematology**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Were samples collected?

Yes ☒

---

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

---

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

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Were samples collected?

Yes ☒

---

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

---

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

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Urine analysis**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Were samples collected?

Yes ☒

---

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

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Category

Serology ☒

---

Not Done

False

---

If Not Done, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Screening**

**Form: Urine Drug Screen**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date of sample collection	13 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

---

Time of sample collection	12:38 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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Alcohol Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the alcohol test performed? Yes ☒

---

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

---

Method used Breath test ☒

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 12:50  
hour:min 24-hour clock

---

Result Negative ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Urine Pregnancy Test**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

Date of Test	13 JAN 2014 DD/MMM/YYYY
--------------	----------------------------

---

Time of Test	13:00 hour:min 24-hour clock
--------------	---------------------------------

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Urine Cotinine Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:17**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

Date of Sample Collection	13 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

---

Time of Sample Collection	12:38 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: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	13 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:20
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	76
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

BUN

---

Code

001040

---

Result

8

---

Unit

MG/DL

---

Lower limit

6

---

Upper limit

24

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

CHOLESTEROL, TOTAL

---

Code

001065

---

Result

181

---

Unit

MG/DL

---

Lower limit

100

---

Upper limit

199

---

Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

PROTEIN, TOTAL, SERUM

---

Code

001073

---

Result

6.8

---

Unit

G/DL

---

Lower limit

6.0

---

Upper limit

8.5

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

ALBUMIN, SERUM

---

Code

001081

---

Result

4.2

---

Unit

G/DL

---

Lower limit

3.5

---

Upper limit

5.5

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

BILIRUBIN, TOTAL

---

Code

001099

---

Result

0.3

---

Unit

MG/DL

---

Lower limit

0.0

---

Upper limit

1.2

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

ALKALINE PHOSPHATASE, S

---

Code

001107

---

Result

73

---

Unit

IU/L

---

Lower limit

39

---

Upper limit

117

---

Flag



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:20
---------------------------	-------

---

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

---

Code	001115
------	--------

---

Result	204
--------	-----

---

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

---

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

---

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

---

Flag	
------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

AST (SGOT)

---

Code

001123

---

Result

16

---

Unit

IU/L

---

Lower limit

0

---

Upper limit

40

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

TRIGLYCERIDES

---

Code

001172

---

Result

121

---

Unit

MG/DL

---

Lower limit

0

---

Upper limit

149

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	13 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:20
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	5.1
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:20
---------------------------	-------

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

CREATININE, SERUM

---

Code

001370

---

Result

0.71

---

Unit

MG/DL

---

Lower limit

0.57

---

Upper limit

1.00

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

ALT (SGPT)

---

Code

001545

---

Result

24

---

Unit

IU/L

---

Lower limit

0

---

Upper limit

32

---

Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

GGT

---

Code

001958

---

Result

15

---

Unit

IU/L

---

Lower limit

0

---

Upper limit

60

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

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

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Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:21**

**Generated On: 20 Jul 2016 11:58:42**

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

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: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:22**

**Generated On: 20 Jul 2016 11:58:42**

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

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Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 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: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type	HEMATOLOGY
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---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:20
---------------------------	-------

---

Analyte Name	WBC
--------------	-----

---

Code	005025
------	--------

---

Result	9.8
--------	-----

---

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

---

Lower limit	3.4
-------------	-----

---

Upper limit	10.8
-------------	------

---

Flag	
------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

RBC

---

Code

005033

---

Result

4.63

---

Unit

X10E6/UL

---

Lower limit

3.77

---

Upper limit

5.28

---

Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

HEMOGLOBIN

---

Code

005041

---

Result

15.3

---

Unit

G/DL

---

Lower limit

11.1

---

Upper limit

15.9

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

HEMATOCRIT

---

Code

005058

---

Result

44.3

---

Unit

%

---

Lower limit

34.0

---

Upper limit

46.6

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

MCV

---

Code

015065

---

Result

96

---

Unit

FL

---

Lower limit

79

---

Upper limit

97

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:20
---------------------------	-------

---

Analyte Name	MCH
--------------	-----

---

Code	015073
------	--------

---

Result	33.0
--------	------

---

Unit	PG
------	----

---

Lower limit	26.6
-------------	------

---

Upper limit	33.0
-------------	------

---

Flag	
------	--

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

MCHC

---

Code

015081

---

Result

34.5

---

Unit

G/DL

---

Lower limit

31.5

---

Upper limit

35.7

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

NEUTROPHILS

---

Code

015107

---

Result

60

---

Unit

%

---

Lower limit

40

---

Upper limit

74

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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

---

Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

LYMPHS

---

Code

015123

---

Result

31

---

Unit

%

---

Lower limit

14

---

Upper limit

46

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

MONOCYTES

---

Code

015131

---

Result

5

---

Unit

%

---

Lower limit

4

---

Upper limit

12

---

Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	13 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:20
Analyte Name	EOS
Code	015149
Result	3
Unit	%
Lower limit	0
Upper limit	5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

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Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

BASOS

---

Code

015156

---

Result

1

---

Unit

%

---

Lower limit

0

---

Upper limit

3

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type	HEMATOLOGY
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---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:20
---------------------------	-------

---

Analyte Name	PLATELETS
--------------	-----------

---

Code	015172
------	--------

---

Result	289
--------	-----

---

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

---

Lower limit	155
-------------	-----

---

Upper limit	379
-------------	-----

---

Flag	
------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

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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

01357100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type	HEMATOLOGY
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---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:20
---------------------------	-------

---

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

---

Code	015909
------	--------

---

Result	5.9
--------	-----

---

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

---

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

---

Upper limit	7.0
-------------	-----

---

Flag	
------	--

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

LYMPHS (ABSOLUTE)

---

Code

015917

---

Result

3.0

---

Unit

X10E3/UL

---

Lower limit

0.7

---

Upper limit

3.1

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

MONOCYTES(ABSOLUTE)

---

Code

015925

---

Result

0.5

---

Unit

X10E3/UL

---

Lower limit

0.1

---

Upper limit

0.9

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	13 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:20
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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:20

---

Analyte Name

BASO (ABSOLUTE)

---

Code

015941

---

Result

0.1

---

Unit

X10E3/UL

---

Lower limit

0.0

---

Upper limit

0.2

---

Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:23**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

01357100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type	URINALYSIS
-----------------	------------

---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:03
---------------------------	-------

---

Analyte Name	SPECIFIC GRAVITY
--------------	------------------

---

Code	13060
------	-------

---

Result	1.005
--------	-------

---

Unit	
------	--

---

Lower limit	1.001
-------------	-------

---

Upper limit	1.035
-------------	-------

---

Flag	
------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(13 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type	URINALYSIS
-----------------	------------

---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:03
---------------------------	-------

---

Analyte Name	PH
--------------	----

---

Code	13078
------	-------

---

Result	7
--------	---

---

Unit	
------	--

---

Lower limit	5
-------------	---

---

Upper limit	8
-------------	---

---

Flag	
------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:03

---

Analyte Name

GLUCOSE

---

Code

13086

---

Result

NORMAL

---

Unit

---

Lower limit

NORMAL

---

Upper limit

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:03

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type	URINALYSIS
-----------------	------------

---

Date of Sample Collection YYYY/MM/DD	13 JAN 2014
---	-------------

---

Subject Number	
----------------	--

---

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

---

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

---

Time of Sample Collection	13:03
---------------------------	-------

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Clinically Significant?

No ☒

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:03

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

13 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

13:03

---

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: 1057**

**Folder: Screening**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:25**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Screening**

**Form: FTND Questionnaire**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	FTND
------	------

---

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

---

Date of assessment	2014 JAN 13
DD/MMM/YYYY	DD/MMM/YYYY

---

Time of assessment	13:48
	hour:min 24-hour clock

---

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

---

1. How soon after you wake up do you smoke your first cigarette?	6-30 minutes <input checked="" type="radio"/>
--	---

---

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input checked="" type="radio"/>
--	-------------------------------------

---

3. Which cigarette would you hate most to give up?	Any other <input checked="" type="radio"/>
--	--

---

4. How many cigarettes per day do you smoke?	21-30 <input checked="" type="radio"/>
--	--

---

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	Yes <input checked="" type="radio"/>
---	--------------------------------------

---

6. Do you smoke even if you are so ill that you are in bed most of the day?	No <input checked="" type="radio"/>
---	-------------------------------------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Screening**

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit  
Smoking**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:20**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Type PROCHASKA STAGE OF  
CHANGE QUESTIONNAIRE:  
INTENTION TO QUIT  
SMOKING

---

Date of assessment 13 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 11:39  
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? 0

---

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Visit

28 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Inclusion Criterion Number	3
----------------------------	---

---

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

---

Result	Yes
--------	-----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	Yes
--------	-----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	Yes
--------	-----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol ).	<input checked="" type="radio"/>
---------------------	--	----------------------------------

---

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

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	No
--------	----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

Exclusion Criterion Number

3

---

Exclusion Criterion

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

---

Result

No

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.
---------------------	---

---

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: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	No
--------	----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	No
--------	----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	No
--------	----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

Exclusion Criterion Number	11
----------------------------	----

---

Exclusion Criterion	The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.
---------------------	--

---

Result	No
--------	----

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic 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: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Result	No
--------	----

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

Were Vitals Signs assessed? Yes ☒

---

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

---

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

---

Time of assessment 12:52  
hour:min 24-hour clock

---

Pulse rate 73  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 109  
mmHg

---

Blood Pressure (diastolic) 60  
mmHg

---

Vital Signs Position of Subject Supine ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Product preference**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

Which Product Arm would you prefer to be randomized  
to:

---

mCC 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

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

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

Has the subject received advices on the risks of  
smoking?

Yes ☒

---

Has a debriefing been performed about THS 2.2?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason:

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System General Appearance ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

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

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Thyroid Gland ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Heart ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Chest ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Lungs ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Gastrointestinal ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Cardiovascular System ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Neurologic ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Skin ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Back ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Musculoskeletal ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Abdomen ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Dentition ☒

---

Outcome Normal ☒

---

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

---

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

---

Not Done False

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done True

---

Not Done; please specify the reason: NOT EXAMINED

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed? Yes ☒

---

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

---

System Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done True

---

Not Done; please specify the reason: NOT EXAMINED

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the physical examination performed?

Yes ☒

---

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

---

System

Other ☒

---

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

---

Outcome \_\_\_\_\_

---

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

---

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

---

Not Done

True

---

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

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Identification of Current Cigarette Brand**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:01**

**Generated On: 20 Jul 2016 11:58:42**

---

Brand name

NATIVE GREEN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: THS 2.2 menthol product test**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the THS 2.2 menthol product trial performed?

Yes ☒

---

If the THS 2.2 menthol product trial was not performed,  
please explain

---

How many THS 2.2 menthol tobacco sticks did the  
subject use on this day?

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: 1057**

**Folder: Admission (Day -2)**

**Form: Smoking History**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

3. How many menthol cigarettes per day has the subject smoked on average during the last 4 weeks? >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: 1057**

**Folder: Admission (Day -2)**

**Form: Weight**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Measurement(s) assessed?

Yes ☒

---

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

---

Time of assessment

12:22  
hour:min 24-hour clock

---

Weight

69.2  
kg

---

Waist circumference

94  
cm

---

BMI

30.3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Urine Drug Screen**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Time of sample collection	12:57 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: 1057**

**Folder: Admission (Day -2)**

**Form: Urine Drug Screen (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Drug type	Result
Opiates	Negative

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Alcohol Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:27**

**Generated On: 20 Jul 2016 11:58:42**

---

Was the alcohol test performed? Yes ☒

---

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

---

Method used Breath test ☒

---

Time of assessment 12:41  
hour:min 24-hour clock

---

Result Negative ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Urine Pregnancy Test**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Time of Test	12:57
	hour:min 24-hour clock

---

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

---

If unclear, please confirm with FSH test

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: CO Breath Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:26**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Actual Time of Assessment	12:38
	hour:min 24-hour clock

---

Result	38
	ppm

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Admission (Day -2)**

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit  
Smoking**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:29**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Type PROCHASKA STAGE OF  
CHANGE QUESTIONNAIRE:  
INTENTION TO QUIT  
SMOKING

---

Date of assessment 28 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 13:28  
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? 0

---

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Visit

29 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Were Vitals Signs assessed? Yes ☒

---

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

---

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

---

Time of assessment 10:18  
hour:min 24-hour clock

---

Pulse rate 67  
beats per minute

---

Respiratory rate 14  
breaths per minute

---

Blood Pressure (systolic) 103  
mmHg

---

Blood Pressure (diastolic) 60  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date DD/MMM/YYYY	29 JAN 2014
---------------------	-------------

---

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

---

Time hour:min 24-hour clock	20:59
--------------------------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

---

Actual Time of Assessment hour:min 24-hour clock	06:48
---	-------

---

Result(ppm)	15
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	12:21
---	-------

---

Result(ppm)	20
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

---

Result(ppm)	32
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	20:53
---	-------

---

Result(ppm)	44
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: 4 hour urine collection**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Start Time	10:09
	hour:min 24-hour clock

---

End Time	14:10
	hour:min 24-hour clock

---

Volume	1064
	mL

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Sample Urine Collection (4 Hour collection)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05115150000337
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	-1
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 JAN 29

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:20  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Moderately ☒

---

2. Did cigarettes taste good?

Quite a lot ☒

---

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?

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?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

9. Did smoking make you dizzy? Not at all ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Moderately ☐

---

12. Did you enjoy smoking? Extremely ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM QUESTIONNAIRE
------	--

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:46 hour:min 24-hour clock
--------------------	---------------------------------

---

Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

---

Do you now smoke cigarettes every day, some days, or not at all?	Every day <input type="radio"/>
---	---------------------------------

---

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	No <input type="radio"/>
--	--------------------------

---

How long has it been since you last smoked a cigarette, even one or two puffs?	<hr/>
---	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:30**

**Generated On: 20 Jul 2016 11:58:42**

---

Do you currently use chewing tobacco, snuff, or snus  
every day, some days, or not at all?

Not at all ☐

NOTE: Snus (Swedish for snuff) is a moist smokeless  
tobacco, usually sold in small pouches that are placed  
under the lip against the gum.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you **NATIVE MENTHOL**  
predominantly smoke in the last 12 months of smoking?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

Days

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

Currently (last 3 months) ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

Days

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

1 year ago ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

5 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

30

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

Days

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

10 years ago ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

30

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

15 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

30

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

Days

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

20 years ago ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

40

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	SMOKING QUESTIONNAIRE
------	-----------------------

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	<hr/>
-----------------	-------

---

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:48 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?	15 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: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

More than 20 years ago ☒

---

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:31**

**Generated On: 20 Jul 2016 11:58:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☒

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☒

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:32**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 29 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:48

---

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: 1057**

**Folder: Baseline (Day -1)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	QSU
------	-----

---

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

Date of assessment	2014 JAN 29
--------------------	-------------

DD/MMM/YYYY

---

Time of assessment	20:19
--------------------	-------

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	Agree <input checked="" type="radio"/>
---	--

---

4. I could control things better right now if I could smoke	Disagree <input checked="" type="radio"/>
---	---

---

5. All I want right now is a cigarette	Somewhat disagree <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: 1057**

**Folder: Baseline (Day -1)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

7. A cigarette would taste good now Strongly agree ☐

---

8. I would do almost anything for a cigarette now Disagree ☐

---

9. Smoking would make me less depressed Disagree ☐

---

10. I am going to smoke as soon as possible Do not agree or disagree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112450000144
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---

Analyte	HPMA
---------	------

---

Sample type	URINE
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---

Result	426
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---

Result Unit	NG/ML
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---

Lab Status	OK
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---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-03
-----------------------	------------

---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112450000144
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---

Analyte	CEMA
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---

Sample type	URINE
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---

Result	80.2
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---

Result Unit	NG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

Detection method	LC-MS/MS
------------------	----------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-03
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112450000144
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---

Analyte	HBMA
---------	------

---

Sample type	URINE
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---

Result	232
--------	-----

---

Result Unit	NG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-03
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112460000579
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---

Analyte	NNAL
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---

Sample type	URINE
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---

Result	290
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---

Result Unit	PG/ML
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---

Lab Status	OK
------------	----

---

Sample comment	
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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	AA99128-04
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112460000579
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---

Analyte	NNN
---------	-----

---

Sample type	URINE
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---

Result	16.9
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---

Result Unit	PG/ML
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---

Lab Status	OK
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---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-04
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	
-----------------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112470000144
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---

Analyte	HEMA
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---

Sample type	URINE
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---

Result	0.877
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---

Result Unit	NG/ML
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---

Lab Status	OK
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Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
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---

Celerion Study Number	AA99128-05
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000419
Analyte	COT
Sample type	URINE
Result	595
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-29
Timepoint-minutes	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112480000419
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---

Analyte	COT-GLUC
---------	----------

---

Sample type	URINE
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---

Result	2330
--------	------

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-06
-----------------------	------------

---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000419
Analyte	NIC
Sample type	URINE
Result	753
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112480000419
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---

Analyte	NIC-GLUC
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---

Sample type	URINE
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---

Result	241
--------	-----

---

Result Unit	NG/ML
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---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

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	AA99128-06
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---

Date of Collection	2014-JAN-29
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---

Timepoint-minutes	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112480000419
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---

Analyte	THCOT
---------	-------

---

Sample type	URINE
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---

Result	1110
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---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
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---

Detection method	LC-MS/MS
------------------	----------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
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---

Celerion Study Number	AA99128-06
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000419
Analyte	THCOT-GLUC
Sample type	URINE
Result	650
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112490000144
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---

Analyte	3-OH BAP
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---

Sample type	URINE
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---

Result	40.5
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---

Result Unit	FG/ML
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---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

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-JAN-29
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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: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112510000144
Analyte	1-NA
Sample type	URINE
Result	33.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112510000144
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---

Analyte	2-NA
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---

Sample type	URINE
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---

Result	11.3
--------	------

---

Result Unit	PG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
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---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-09
-----------------------	------------

---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112510000144
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---

Analyte	4-ABP
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---

Sample type	URINE
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---

Result	8.82
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---

Result Unit	PG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99128-09
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112510000144
Analyte	O-TOL
Sample type	URINE
Result	56.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112530000092
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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	
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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-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:33**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112540000092
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---

Analyte	IPF2A-III
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---

Sample type	URINE
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---

Result	99.4
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---

Result Unit	PG/ML
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---

Lab Status	OK
------------	----

---

Sample comment	
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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-JAN-29
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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: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115190000012
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---

Analyte	1-OHP
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---

Sample type	URINE
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---

Result	40.7
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---

Result Unit	PG/ML
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---

Lab Status	OK
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---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99598-03
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---

Date of Collection	2014-JAN-29
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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: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115170003405
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---

Analyte	SBMA
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---

Sample type	URINE
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---

Result	1.88
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---

Result Unit	NG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99598-01
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115170003405
----------------	----------------

---

Analyte	SPMA
---------	------

---

Sample type	URINE
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---

Result	0.256
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---

Result Unit	NG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	-1
--------------	----

---

Celerion Study Number	AA99598-01
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
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---

Urine Start Day	
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115180001101
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Analyte	MHBMA
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---

Sample type	URINE
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Result	BLQ<(0.100)
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---

Result Unit	NG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	
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---

Celerion Study Number	AA99598-02
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---

Date of Collection	2014-JAN-29
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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: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:34**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115160000144
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---

Analyte	CREATININE
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---

Sample type	URINE
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---

Result	19.0
--------	------

---

Result Unit	MG/DL
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	SPECTROPHOTOMETRIC
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---

Planned time point (Hour)	0
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---

Day of Visit	-1
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---

Celerion Study Number	AA99128-14
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---

Date of Collection	2014-JAN-29
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	
-----------------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Visit

30 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Randomization**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

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Randomization number (4 digits)	4003
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---

Allocation Arm	mCC <input checked="" type="radio"/>
----------------	--------------------------------------

---

Cigarette Consumption	Greater than 19 conventional menthol cigarettes per day <input checked="" type="radio"/>
-----------------------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Were Vitals Signs assessed? Yes ☒

---

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

---

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

---

Time of assessment 10:30  
hour:min 24-hour clock

---

Pulse rate 55  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 129  
mmHg

---

Blood Pressure (diastolic) 68  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Gas Transfer**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:01**

**Generated On: 20 Jul 2016 11:58:42**

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY  
WERE NOT RESULTED

Category

Position

SITTING

Time of assessment

DLCO value

KCO value

DLCO/VA value

Interpretation

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lung Volume Measurements**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:01**

**Generated On: 20 Jul 2016 11:58:42**

Were the Lung Volume Measurements performed?

No ☐

If No, please specify the reason:

TEST PERFORMED BUT THEY  
WERE NOT RESULTED

Category

Position

SITTING

Time of assessment

VC value

TLC value

IC value

FRC value

Interpretation

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Spirometry with a short-acting bronchodilator**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:01**

**Generated On: 20 Jul 2016 11:58:42**

Was the Spirometry with a short-acting bronchodilator  
performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY  
WERE NOT RESULTED

Category

With short-acting  
bronchodilator ☒

Position

SITTING

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

Predicted FEV1 value

Percent of predicted FEV1 value

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Spirometry with a short-acting bronchodilator**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:01**

**Generated On: 20 Jul 2016 11:58:42**

---

Calculated ratio between FEV1/FVC

---

MEF 25/75 value

---

Interpretation

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Haematology**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Were samples collected?

Yes ☒

---

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

---

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

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Were samples collected?

Yes ☒

---

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

---

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

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Urine analysis**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Were samples collected?

Yes ☒

---

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

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

---

Time hour:min 24-hour clock	20:38
--------------------------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

---

Time hour:min 24-hour clock	20:38
--------------------------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CoHb Blood Sample <D0> (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

---

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

---

Time hour:min 24-hour clock	07:09
--------------------------------	-------

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CoHb Blood Sample <D0> (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

---

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

---

Time hour:min 24-hour clock	20:38
--------------------------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterols**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

---

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

---

Time hour:min 24-hour clock	07:09
--------------------------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

---

Actual Time of Assessment hour:min 24-hour clock	09:40
---	-------

---

Result(ppm)	12
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	12:27
---	-------

---

Result(ppm)	24
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	16:22
---	-------

---

Result(ppm)	44
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	20:00 - 21:30 
----------------	---

---

Actual Time of Assessment hour:min 24-hour clock	20:23
---	-------

---

Result(ppm)	38
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CYP2A6 activity Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date of sample collection  
DD/MMM/YYYY

Time of sample collection  
hour:min 24-hour clock

Parameter

---

30 JAN 2014

07:09

trans-3'-hydroxyc  
otinine

---

30 JAN 2014

07:09

cotinine

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: CYP1A2 activity Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Time of caffeine tablet intake	10:20
	hour:min 24-hour clock

---

Sample collection 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
30 JAN 2014	16:28	Caffeine
30 JAN 2014	16:28	Paraxanthine

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,  
sICAM-1, HbA1c, Apo A1, Apo B**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

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

---

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

---

Time hour:min 24-hour clock	07:09
--------------------------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Start Date	30 JAN 2014 DD/MMM/YYYY
------------	----------------------------

---

Start Time	07:00 hour:min 24-hour clock
------------	---------------------------------

---

End Date	31 JAN 2014 DD/MMM/YYYY
----------	----------------------------

---

End Time	06:07 hour:min 24-hour clock
----------	---------------------------------

---

Volume	2895 mL
--------	------------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 30  
DD/MMM/YYYY

---

Time of assessment

06:03  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

---

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Moderate ☐

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? Slight ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Moderate ☐

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? Slight ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 30  
DD/MMM/YYYY

---

Time of assessment

06:02  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs?

No ☒

---

If YES, please answer the following questions:

---

First Question: Cough Impact Scale  
How much is your cough bothering you?

-9

---

Second Question: Cough Intensity Scale:  
How intense is your cough?

Not Applicable ☒

---

Third Question: Cough Frequency Scale:  
How frequently do you normally have to cough each  
day?

Not Applicable ☒

---

Fourth Question: Sputum Production  
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Bio-banking (Transcriptomics)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

---

Time of Sample Collection

07:09  
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Bio-banking (Biomarkers of exposure and risk markers)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Was a Bio-banking sample for biomarkers of exposure  
and risk markers taken?

Yes ☒

---

Time of Sample Collection

07:09  
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Bio-banking (nasal epithelial collection/buccal collection)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input type="radio"/>
---	---------------------------

---

Time of Buccal Collection	18:51
	hour:min 24-hour clock

---

Time of Nasal Epithelial Collection	18:49
	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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1029

---

Battery Name TRIGLYCERIDES

---

Lab Test ID RCT19

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	171
Reported Numeric Result	171
Reference Range low	52
Reference Range high	262
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1092

---

Battery Name FASTING GLUCOSE

---

Lab Test ID RCT142

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input 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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition 

---

---

Battery ID RC272

---

Battery Name TOTAL CHOLESTEROL

---

Lab Test ID RCT20

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	174
Reported Numeric Result	174
Reference Range low	171
Reference Range high	291
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

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Subject Sex F

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Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

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Actual Collection Time 07:09

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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 RCT12

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

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Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT13

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.9
Reported Numeric Result	3.9
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

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Battery ID RC9255

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Battery Name CHEMISTRY PANEL

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Lab Test ID RCT1407

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	65
Reported Numeric Result	65
Reference Range low	35
Reference Range high	123
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	215
Reported Numeric Result	215
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	137
Reported Numeric Result	137
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

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Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.8
Reported Numeric Result	3.8
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

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Subject Sex F

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Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.8
Reported Numeric Result	0.8
Reference Range low	0.4
Reference Range high	1.1
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	26
Reported Numeric Result	26
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	23
Reported Numeric Result	23
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.52
Reported Numeric Result	0.52
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.36
Reported Numeric Result	0.36
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.07
Reported Numeric Result	0.07
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	292
Reported Numeric Result	292
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	58.6
Reported Numeric Result	58.6
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	32.1
Reported Numeric Result	32.1
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	5.1
Reported Numeric Result	5.1
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
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---

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	3.5
Reported Numeric Result	3.5
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
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---

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
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---

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	34
Reference Range high	48
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	4.1
Reference Range high	5.6
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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---

Specimen Condition	<hr/>
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---

Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	98
Reported Numeric Result	98
Reference Range low	79
Reference Range high	98
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.0
Reported Numeric Result	15.0
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10.16
Reported Numeric Result	10.16
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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Lab Test Name


RBC MORPHOLOGY 1

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Test ID

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.95
Reported Numeric Result	5.95
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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Actual Collection Time	07:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.27
Reported Numeric Result	3.27
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
------------------------	-------

---

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	UAT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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Lab Test Name


UR NITRITE

---

Test ID

---

Test Status

Done 

---

Reported Text Result

+2

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	<hr/>
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---

Subject Sex	F
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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	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

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	UAT2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.011
Reported Numeric Result	1.011
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	<hr/>
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---

Subject Sex	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
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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	UAT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225510

---

Actual Collection Date 2014 01 30

---

Actual Collection Time 07:09

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT43

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

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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	F
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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	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	<hr/>
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---

Battery ID	UA1538
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---

Battery Name	URINE MACRO PANEL
--------------	-------------------

---

Lab Test ID	UAT49
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---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	UR PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	NEGATIVE
Reported Numeric Result	
Reference Range low	
Reference Range high	
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

---

Subject ID or Number	<hr/>
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---

Subject Sex	F
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---

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

---

Visit Name	<hr/>
------------	-------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Lab Test Name


UR GLUCOSE

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NORMAL

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

---

Subject ID or Number	<hr/>
----------------------	-------

---

Subject Sex	F
-------------	---

---

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

---

Visit Name	<hr/>
------------	-------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

Lab Test Name

UR BILIRUBIN

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:37**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (1)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

---

Analyte code	22RHCRL
--------------	---------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	9.46
-------------------------------	------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (2)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

---

Analyte code	24RHCRL
--------------	---------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	6.56
-------------------------------	------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (3)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	25-HYDROXYCHOLESTEROL
---------	-----------------------

---

Analyte code	25HCRL
--------------	--------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	4.70
-------------------------------	------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (4)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

---

Analyte code	27HCRL
--------------	--------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	11.60
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (5)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

---

Analyte code	4BHCRL
--------------	--------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	10.66
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (6)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

---

Analyte code	5A6AECNL
--------------	----------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	12.46
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (7)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

---

Analyte code	5B6BECNL
--------------	----------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	26.83
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (8)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

---

Analyte code	6AH5ACNL
--------------	----------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	13.70
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (9)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	7-KETOCHOLESTEROL
---------	-------------------

---

Analyte code	7KCRL
--------------	-------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	15.43
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (10)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	7A-HYDROXYCHOLESTEROL
---------	-----------------------

---

Analyte code	7AHCRL
--------------	--------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	13.46
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (11)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

---

Analyte code	7BHCRL
--------------	--------

---

Result	
--------	--

---

Result Unit	NG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	12.86
-------------------------------	-------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (12)**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Accession number	3122551039
-------------------------	------------

---

Analyte	CHOLESTEROL
---------	-------------

---

Analyte code	CHOL
--------------	------

---

Result	
--------	--

---

Result Unit	MG/ML
-------------	-------

---

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

---

Lower limit of quantification	0.50
-------------------------------	------

---

Date of Collection DD MMM YYYY	
-----------------------------------	--

---

Collection time hh:mm 24 hour clock	
--	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05115150000338
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05115150000339
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 JAN 30

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:12  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Quite a lot ☒

---

2. Did cigarettes taste good?

Quite a lot ☒

---

3. Did you enjoy the sensation in your throat and chest?

Quite a lot ☒

---

4. Did smoking calm you down?

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?

Not at all ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

9. Did smoking make you dizzy? Not at all ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Little ☐

---

12. Did you enjoy smoking? Extremely ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

---

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

---

Reason not done	
-----------------	--

---

Date of assessment	30 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

---

Time of assessment	20:18 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 :	CIGARETTE SMOKES MUCH FASTER. SEEMS THAT EACH DRAG/PUFF IS DEEPER.
---	--

---

2. You enjoy smoking with the device as much as without it.	Disagree <input type="radio"/>
---	--------------------------------

---

If you disagree or strongly disagree, please describe :	FEELS VERY LONG AND UNCOMFORTABLE.
---	---------------------------------------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:35**

**Generated On: 20 Jul 2016 11:58:42**

---

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. Agree ☐

---

If you disagree or strongly disagree, please describe : \_\_\_\_\_

---

5. Your smoking is disturbed by the device. Agree ☐

---

If you agree or strongly agree, please describe : IT FEELS DIFFERENT AND  
MAKES ME ACTUALLY THINK  
ABOUT WHAT I AM DOING.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

Type	QSU
------	-----

---

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

---

Date of assessment	2014 JAN 30
--------------------	-------------

DD/MMM/YYYY

---

Time of assessment	20:11
--------------------	-------

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	Somewhat disagree <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	Somewhat disagree <input checked="" type="radio"/>
---	--

---

5. All I want right now is a cigarette	Somewhat disagree <input checked="" type="radio"/>
--	--

---

6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
-----------------------------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:36**

**Generated On: 20 Jul 2016 11:58:42**

---

7. A cigarette would taste good now Strongly agree ☐

---

8. I would do almost anything for a cigarette now Somewhat disagree ☐

---

9. Smoking would make me less depressed Disagree ☐

---

10. I am going to smoke as soon as possible Agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

---

Subject ID or Number	1057
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---

Subject Sex	F
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---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
--------------------	--

---

Battery ID	CG267
------------	-------

---

Battery Name	FIBRINOGEN
--------------	------------

---

Lab Test ID	CGT285
-------------	--------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	357
Reported Numeric Result	357
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

---

Subject ID or Number	1057
----------------------	------

---

Subject Sex	F
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---

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

Visit Name	DAY0
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---

Visit Type	Scheduled <input checked="" type="radio"/>
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---

Accession ID	V225510
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---

Actual Collection Date	2014 01 30
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---

Actual Collection Time	07:09
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---

Specimen Condition	
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---

Battery ID	CN236
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---

Battery Name	HOMOCYSTEINE
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---

Lab Test ID	CNT145
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.79
Reported Numeric Result	5.79
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	1057
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---

Subject Sex	F
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---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
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---

Battery ID	IM2293
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---

Battery Name	SICAM-1
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---

Lab Test ID	IMT1768
-------------	---------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	310.2
Reported Numeric Result	310.2
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	1057
----------------------	------

---

Subject Sex	F
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---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
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---

Battery ID	HM1054
------------	--------

---

Battery Name	HEMOGLOBIN A1C
--------------	----------------

---

Lab Test ID	HMT370
-------------	--------

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Lab Test Name


HEMOGLOBIN  
A1C,VARIANT(-70)

---

Test ID

---

Test Status

Done 

---

Reported Text Result

5.2

---

Reported Numeric Result

5.2

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

---

Subject ID or Number	1057
----------------------	------

---

Subject Sex	F
-------------	---

---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
--------------------	--

---

Battery ID	RC6871
------------	--------

---

Battery Name	HDL
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---

Lab Test ID	RCT1684
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	40
Reported Numeric Result	40
Reference Range low	37
Reference Range high	92
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	1057
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---

Subject Sex	F
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---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
--------------------	--

---

Battery ID	SC3249
------------	--------

---

Battery Name	HS-CRP
--------------	--------

---

Lab Test ID	SCT1528
-------------	---------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.275
Reported Numeric Result	0.275
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	1057
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---

Subject Sex	F
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---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
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---

Battery ID	SC3582
------------	--------

---

Battery Name	APOLIPOPROTEIN
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---

Lab Test ID	SCT3639
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	APOLIPOPROTEIN A1, RAND
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	136
Reported Numeric Result	136
Reference Range low	125
Reference Range high	215
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: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
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---

Subject ID or Number	1057
----------------------	------

---

Subject Sex	F
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---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
--------------------	--

---

Battery ID	SC3582
------------	--------

---

Battery Name	APOLIPOPROTEIN
--------------	----------------

---

Lab Test ID	SCT3643
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	96
Reported Numeric Result	96
Reference Range low	55
Reference Range high	125
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

---

Subject ID or Number	1057
----------------------	------

---

Subject Sex	F
-------------	---

---

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

---

Visit Name	DAY0
------------	------

---

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

---

Accession ID	V225510
--------------	---------

---

Actual Collection Date	2014 01 30
------------------------	------------

---

Actual Collection Time	07:09
------------------------	-------

---

Specimen Condition	
--------------------	--

---

Battery ID	RC9267
------------	--------

---

Battery Name	LDL
--------------	-----

---

Lab Test ID	RCT2394
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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---

Test ID	<hr/>
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---

Test Status	Done <input checked="" type="radio"/>
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---

Reported Text Result	101
----------------------	-----

---

Reported Numeric Result	101
-------------------------	-----

---

Reference Range low	90
---------------------	----

---

Reference Range high	215
----------------------	-----

---

Range Units	MG/DL
-------------	-------

---

Conventional Text Result	<hr/>
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---

Conventional Numeric Result	<hr/>
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---

Conventional Reference Range Low	<hr/>
----------------------------------	-------

---

Conventional Reference Range High	<hr/>
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---

Conventional Units	<hr/>
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---

SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:58**

**Generated On: 20 Jul 2016 11:58:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112450000146
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---

Analyte	HPMA
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---

Sample type	URINE
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---

Result	511
--------	-----

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-03
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	0
-----------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112450000146
Analyte	CEMA
Sample type	URINE
Result	89.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112450000146
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---

Analyte	HBMA
---------	------

---

Sample type	URINE
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---

Result	267
--------	-----

---

Result Unit	NG/ML
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---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-03
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	0
-----------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112460000608
Analyte	NNAL
Sample type	URINE
Result	321
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112460000608
Analyte	NNN
Sample type	URINE
Result	20.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112470000146
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---

Analyte	HEMA
---------	------

---

Sample type	URINE
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---

Result	0.893
--------	-------

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
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---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-05
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---

Date of Collection	2014-JAN-30
--------------------	-------------

---

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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000421
Analyte	COT
Sample type	URINE
Result	632
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

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Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000421
Analyte	COT-GLUC
Sample type	URINE
Result	2710
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000421
Analyte	NIC
Sample type	URINE
Result	721
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000421
Analyte	NIC-GLUC
Sample type	URINE
Result	462
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-30
Timepoint-minutes	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

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Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112480000421
Analyte	THCOT
Sample type	URINE
Result	1320
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112480000421
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Analyte	THCOT-GLUC
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---

Sample type	URINE
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---

Result	736
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---

Result Unit	NG/ML
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---

Lab Status	OK
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Sample comment	
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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	0
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Celerion Study Number	AA99128-06
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---

Date of Collection	2014-JAN-30
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---

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

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Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112490000146
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Analyte	3-OH BAP
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Sample type	URINE
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Result	65.4
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	
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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	0
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JAN-30
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine)**

**Generated On: 20 Jul 2016 11:58:42**

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Sample type

PLASMA

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112500000058
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	456
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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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	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-JAN-30
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	0
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112500000058
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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---

Result	858
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---

Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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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	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-JAN-30
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112510000146
Analyte	1-NA
Sample type	URINE
Result	61.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112510000146
Analyte	2-NA
Sample type	URINE
Result	19.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112510000146
Analyte	4-ABP
Sample type	URINE
Result	13.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112510000146
Analyte	O-TOL
Sample type	URINE
Result	77.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112530000094
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Analyte	11-DTXB2
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---

Sample type	URINE
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---

Result	375
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Result Unit	PG/ML
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---

Lab Status	OK
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Sample comment	
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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	0
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---

Celerion Study Number	AA99128-11
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---

Date of Collection	2014-JAN-30
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05112540000094
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Analyte	IPF2A-III
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---

Sample type	URINE
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---

Result	110
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---

Result Unit	PG/ML
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---

Lab Status	OK
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Sample comment	
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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	0
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---

Celerion Study Number	AA99128-12
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Date of Collection	2014-JAN-30
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

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Urine End Day	1
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05113320000163
Analyte	AMES
Sample type	URINE
Result	.
Result Unit	REV/ML
Lab Status	OK
Sample comment	ND
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

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Sample Barcode	05115190000014
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Analyte	1-OHP
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Sample type	URINE
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---

Result	53.1
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---

Result Unit	PG/ML
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---

Lab Status	OK
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---

Sample comment	
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---

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	AA99598-03
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---

Date of Collection	2014-JAN-30
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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: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
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---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05115170002679
Analyte	SBMA
Sample type	URINE
Result	1.88
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05115170002679
Analyte	SPMA
Sample type	URINE
Result	0.293
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-JAN-30
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115180001103
----------------	----------------

---

Analyte	MHBMA
---------	-------

---

Sample type	URINE
-------------	-------

---

Result	BLQ<(0.100)
--------	-------------

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
------------------	----------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99598-02
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	0
-----------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05115160000146
----------------	----------------

---

Analyte	CREATININE
---------	------------

---

Sample type	URINE
-------------	-------

---

Result	27.8
--------	------

---

Result Unit	MG/DL
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-14
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	
-------------------	--

---

Urine Start Day	0
-----------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:04**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	1
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112430000248
----------------	----------------

---

Analyte	COT
---------	-----

---

Sample type	PLASMA
-------------	--------

---

Result	206
--------	-----

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
------------------	----------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-01
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	0
-------------------	---

---

Urine Start Day	
-----------------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	0
---------------	---

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112430000248
----------------	----------------

---

Analyte	NIC
---------	-----

---

Sample type	PLASMA
-------------	--------

---

Result	15.4
--------	------

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
------------------	----------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-01
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	0
-------------------	---

---

Urine Start Day	
-----------------	--

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	0
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Sample Barcode	05112520000040
----------------	----------------

---

Analyte	COT
---------	-----

---

Sample type	PLASMA
-------------	--------

---

Result	148
--------	-----

---

Result Unit	NG/ML
-------------	-------

---

Lab Status	OK
------------	----

---

Sample comment	
----------------	--

---

Detection method	LC-MS/MS
------------------	----------

---

Planned time point (Hour)	0
---------------------------	---

---

Day of Visit	0
--------------	---

---

Celerion Study Number	AA99128-10
-----------------------	------------

---

Date of Collection	2014-JAN-30
--------------------	-------------

---

Timepoint-minutes	0
-------------------	---

---

Urine Start Day	
-----------------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	0
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

Sample Barcode	05112520000040
Analyte	THCOT
Sample type	PLASMA
Result	97.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-JAN-30
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:03**

**Generated On: 20 Jul 2016 11:58:42**

---

Urine End Day	0
---------------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Visit

31 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Were Vitals Signs assessed?

No ☒

---

If No, please specify the reason:

SUBJECT WITHDREW  
CONSENT AND EARLY  
TERMED

---

Has the subject smoked within 15 minutes prior to  
assessment

---

Time of assessment

---

Pulse rate

---

Respiratory rate

---

Blood Pressure (systolic)

---

Blood Pressure (diastolic)

---

Vital Signs Position of Subject

Supine ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Not Done

True

---

If Not Done, please specify the reason:

SUBJECT WITHDREW  
CONSENT AND EARLY  
TERMED

---

Date  
DD/MMM/YYYY

---

Time  
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Not Done	True
----------	------

---

If Not Done, please specify the reason:

SUBJECT WITHDREW  
CONSENT AND EARLY  
TERMED

---

Date  
DD/MMM/YYYY

---

Time  
hour:min 24-hour clock

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Not Done	True
----------	------

---

If Not Done, please specify the reason:

SUBJECT WITHDREW  
CONSENT AND EARLY  
TERMED

---

Date  
DD/MMM/YYYY

---

Timepoint

20:00 - 21:30 ☒

---

Time  
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	False
---------------------	-------

---

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

---

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

---

Actual Time of Assessment hour:min 24-hour clock	07:06
---	-------

---

Result(ppm)	21
-------------	----

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	True
---------------------	------

---

If Not Done, please specify the reason:	SUBJECT WITHDREW CONSENT AND EARLY TERMED
---	---

---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

---

Result(ppm)	<hr/>
-------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	True
---------------------	------

---

If Not Done, please specify the reason:	SUBJECT WITHDREW CONSENT AND EARLY TERMED
---	---

---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

---

Result(ppm)	<hr/>
-------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Assessment not done	True
---------------------	------

---

If Not Done, please specify the reason:	SUBJECT WITHDREW CONSENT AND EARLY TERMED
---	---

---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

---

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

---

Result(ppm)	<hr/>
-------------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Start Time	06:07
	hour:min 24-hour clock

---

End Date	31 JAN 2014
	DD/MMM/YYYY

---

End Time	08:48
	hour:min 24-hour clock

---

Volume	<hr/>
--------	-------

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 31  
DD/MMM/YYYY

---

Time of assessment

07:01  
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?

Slight ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Moderate ☐

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? Slight ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Mild ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:05**

**Generated On: 20 Jul 2016 11:58:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Day 1**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 31  
DD/MMM/YYYY

---

Time of assessment

07:00  
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: 1057**

**Folder: Discharge (Confinement)**

**Form: Date of Discharge**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:01**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of Visit

31 JAN 2014  
DD/MMM/YYYY

---

Discharge Time

08:14  
hour:min 24-hour clock

---

Is the subject continuing in the ambulatory period?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	06:48
----------------------	-------

---

Time of butt return	06:59
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	07:28
----------------------	-------

---

Time of butt return	07:37
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	08:24
----------------------	-------

---

Time of butt return	08:35
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	09:28
----------------------	-------

---

Time of butt return	09:35
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	10:19
----------------------	-------

---

Time of butt return	10:27
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	11:19
----------------------	-------

---

Time of butt return	11:27
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	12:25
----------------------	-------

---

Time of butt return	12:35
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	13:04
----------------------	-------

---

Time of butt return	13:12
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	13:44
----------------------	-------

---

Time of butt return	13:53
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	14:46
----------------------	-------

---

Time of butt return	14:53
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	15:46
----------------------	-------

---

Time of butt return	15:54
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	16:29
----------------------	-------

---

Time of butt return	16:39
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	17:29
----------------------	-------

---

Time of butt return	17:38
---------------------	-------

---

CC with SODIM?	False
----------------	-------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	_____
---------------------	-------

---

SODIM sample holder number	_____
----------------------------	-------

---

SODIM file number	_____
-------------------	-------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	18:44
----------------------	-------

---

Time of butt return	18:52
---------------------	-------

---

CC with SODIM?	False
----------------	-------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	_____
---------------------	-------

---

SODIM sample holder number	_____
----------------------------	-------

---

SODIM file number	_____
-------------------	-------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	19:30
----------------------	-------

---

Time of butt return	19:37
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	21:06
----------------------	-------

---

Time of butt return	21:14
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	21:54
----------------------	-------

---

Time of butt return	22:03
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

---

Visit	Day -1 <input checked="" type="radio"/>
-------	---

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	22:24
----------------------	-------

---

Time of butt return	22:32
---------------------	-------

---

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: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	09:42
----------------------	-------

---

Time of butt return	09:48
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201001
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	10:51
----------------------	-------

---

Time of butt return	10:59
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201002
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	11:35
----------------------	-------

---

Time of butt return	11:43
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201003
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	12:05
----------------------	-------

---

Time of butt return	12:13
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201004
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	12:51
----------------------	-------

---

Time of butt return	12:58
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201005
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	13:29
----------------------	-------

---

Time of butt return	13:38
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201006
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	14:44
----------------------	-------

---

Time of butt return	14:52
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201007
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	15:35
----------------------	-------

---

Time of butt return	15:43
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201008
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	16:07
----------------------	-------

---

Time of butt return	16:16
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201009
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	16:47
----------------------	-------

---

Time of butt return	16:57
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201010
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	17:30
----------------------	-------

---

Time of butt return	17:39
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201011
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	18:24
----------------------	-------

---

Time of butt return	18:32
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201013
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	19:29
----------------------	-------

---

Time of butt return	19:37
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201014
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	20:42
----------------------	-------

---

Time of butt return	20:50
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201015
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	21:05
----------------------	-------

---

Time of butt return	21:11
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201015
-------------------	----------------------

---

Comment	SUBJECT COMPLAINS THAT MACHINE TURNED OFF DURING SMOKING EVENT.
---------	---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

---

Visit	Day 0 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	22:24
----------------------	-------

---

Time of butt return	22:33
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201016
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	31 JAN 2014
------------------------------------	-------------

---

Visit	Day 1 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	07:08
----------------------	-------

---

Time of butt return	07:15
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201017
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	31 JAN 2014
------------------------------------	-------------

---

Visit	Day 1 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	07:37
----------------------	-------

---

Time of butt return	07:44
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201018
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	31 JAN 2014
------------------------------------	-------------

---

Visit	Day 1 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	08:15
----------------------	-------

---

Time of butt return	08:23
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201019
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	31 JAN 2014
------------------------------------	-------------

---

Visit	Day 1 <input checked="" type="radio"/>
-------	--

---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

Time of distribution	09:03
----------------------	-------

---

Time of butt return	09:10
---------------------	-------

---

CC with SODIM?	True
----------------	------

---

CC not compatible?	False
--------------------	-------

---

SODIM device number	149
---------------------	-----

---

SODIM sample holder number	0201
----------------------------	------

---

SODIM file number	08DY0149COHC10201020
-------------------	----------------------

---

Comment	_____
---------	-------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-mCC (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:06**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-THS menthol**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product administration-THS menthol (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of product use DD/MMM/YYYY	28 JAN 2014
------------------------------------	-------------

---

---

Visit	Day -2 <input type="radio"/>
-------	------------------------------

---

---

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

---

---

If type of Product Use different from the randomization please explain	PRODUCT TEST
---	--------------

---

---

Time of distribution	18:26
----------------------	-------

---

---

Time of product return	<hr/>
------------------------	-------

---

---

SODIM device number	<hr/>
---------------------	-------

---

---

SODIM sample holder number	<hr/>
----------------------------	-------

---

---

Tobacco plug kit number	<hr/>
-------------------------	-------

---

---

Tobacco plug vial number	<hr/>
--------------------------	-------

---

---

SODIM file number	<hr/>
-------------------	-------

---

---

Comment	<hr/>
---------	-------

---

---

Batch Number	B08545
--------------	--------

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Product Use**

**Form: Product administration-THS menthol (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (1)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (2)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (3)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (4)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (5)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (6)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (7)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (8)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (9)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (10)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (11)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (12)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (13)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (14)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number \_\_\_\_\_

---

File Status \_\_\_\_\_

---

Rejection / Error reason \_\_\_\_\_

---

Date of analysis  
DD/MMM/YYYY \_\_\_\_\_

---

Operator \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Modified File Number \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (15)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (16)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (17)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Topography files status for mCC (18)**

**Generated On: 20 Jul 2016 11:58:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product use diary(Paper)**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:02**

**Generated On: 20 Jul 2016 11:58:42**

---

Was paper questionnaire used?

No ☒

---

Reason not done

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Product Use**

**Form: Product use diary(Paper) (1)**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:02**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Product Use**

**Form: Product use diary(Paper) (1)**

**Data signed: (hcoleman1) 18 Jun 2015 19:54:02**

**Generated On: 20 Jul 2016 11:58:42**

---

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: 1057**

**Folder: Adverse Events**

**Form: Adverse Events Y/N**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

Was there any Adverse Event for this subject?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

AE Identifier	1
---------------	---

---

Adverse Event	CONSTIPATION
---------------	--------------

---

Start Date	27 JAN 2014
------------	-------------

DD/MMM/YYYY

---

End Date	30 JAN 2014
----------	-------------

DD/MMM/YYYY

---

Ongoing at final contact	No <input checked="" type="radio"/>
--------------------------	-------------------------------------

---

Severity	Mild Adverse Event <input checked="" type="radio"/>
----------	---

---

Serious AE	No <input checked="" type="radio"/>
------------	-------------------------------------

---

Seriousness Criteria

---

Treatment given	No <input checked="" type="radio"/>
-----------------	-------------------------------------

---

AE related to Study Procedure	Not Related <input checked="" type="radio"/>
-------------------------------	--

---

Relationship to mCC/THS	Not Related <input checked="" type="radio"/>
-------------------------	--

---

AE expectedness

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

Action taken with study product

Not Applicable ☒

---

Other action taken

---

---

Outcome

Recovered or Resolved ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication Y/N**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

Has the subject taken previous or concomitant  
medication?

---

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

---

Brand Name	ESTRADIOL
------------	-----------

---

Start Date DD/MMM/YYYY	UN UNK 2011
---------------------------	-------------

---

Stop Date DD/MMM/YYYY	
--------------------------	--

---

Ongoing at final contact	True
--------------------------	------

---

Total Daily dose - Dose	2
-------------------------	---

---

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

---

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

---

Indication	HORMONE REPLACEMENT
------------	---------------------

---

Concomitant Disease Number	NA
----------------------------	----

---

AE Number	
-----------	--

---

Other	
-------	--

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1057**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:57:10**

**Generated On: 20 Jul 2016 11:58:42**

Brand Name	SIMVASTATIN
Start Date DD/MMM/YYYY	UN UNK 2011
Stop Date DD/MMM/YYYY	
Ongoing at final contact	True
Total Daily dose - Dose	40
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Concomitant Disease Number	6
AE Number	
Other	



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Form: End of study**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:15**

**Generated On: 20 Jul 2016 11:58:42**

---

End of study date

28 FEB 2014  
DD/MMM/YYYY

---

Has the subject completed the study ?

No ☒

---

If No, please specify the reason:

Withdrawal by Subject ☒

---

Details:

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Form: Consent Withdrawal**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:15**

**Generated On: 20 Jul 2016 11:58:42**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1057**

**Form: Withdrawal**

**Data signed: (hfarmer1) 26 Mar 2015 14:56:15**

**Generated On: 20 Jul 2016 11:58:42**

---

Date of withdrawal	31 JAN 2014 DD/MMM/YYYY
--------------------	-------------------------

---

Did the subject withdraw it's consent from the main study?	Yes <input checked="" type="radio"/>
--	--------------------------------------

---

If available, please provide details	THE SUBJECT WITHDREW CONSENT
--------------------------------------	---------------------------------

---

Did the subject withdraw from the Protected Health Information (PHI)?	No <input type="radio"/>
---	--------------------------

---

Did the subject confirm that samples collected up to the time of withdrawal can be analysed?	Yes <input checked="" type="radio"/>
--	--------------------------------------

---