

Subject Case Report Forms

1233 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 21:44:07

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Form: Subject

Data signed: (hfarmer1) 29 Mar 2015 18:58:19

Generated On: 20 Jul 2016 21:44:07

Screening number	1233
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 29 Mar 2015 18:58:20

Generated On: 20 Jul 2016 21:44:07

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

28 MAR 2014
DD/MMM/YYYY

Randomization Date

Randomization Time

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Date of Visit

12 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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

Yes ☒

Consent Date

12 MAR 2014
DD/MMM/YYYY

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

Yes ☒

Consent Date

12 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

*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: 1233**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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).
---------------------	---

Result	Yes
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*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: 1233**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

*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: 1233**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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).
---------------------	---

Result	No
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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: 1233

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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).
---------------------	--

Result	No
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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: 1233

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

Exclusion Criterion Number	7
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .
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Result	No
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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: 1233**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

Exclusion Criterion Number	10
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Exclusion Criterion	The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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

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

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: 1233**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

Exclusion Criterion Number	18
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Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).
---------------------	--

Result	No <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: 1233**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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).
---------------------	--

Result	No
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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: 1233**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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.	<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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

Exclusion Criterion Number	21
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Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
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Result	NA
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 29 Mar 2015 18:58:21

Generated On: 20 Jul 2016 21:44:07

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

Result	NA
--------	----

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 29 Mar 2015 18:58:20

Generated On: 20 Jul 2016 21:44:07

Date of Birth

(b)

Sex

Male ☒

Race

White ☒

Other, specify _____

Ethnicity

Not Hispanic ☒

Date the Subject signed the Informed Consent

12 MAR 2014
DD/MMM/YYYY

Time the Subject signed the Informed Consent

10:00
hour:min 24-hour clock

Age(Derived)

33

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection

12 MAR 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: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection	12 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	01
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Diagnosis Description	TATTOOS RIGHT BOTH ARMS MILD
-----------------------	---------------------------------

Onset Date DD/MMM/YYYY	UN UNK 2003
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection	12 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	2
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Diagnosis Description	SIGNIFICANT SCARS RIGHT ANKLE BROKEN MILD
-----------------------	--

Onset Date DD/MMM/YYYY	UN UNK 2010
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection	12 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	3
--------	---

Diagnosis Description	SIGNIFICANT LACERATIONS UNDER BELLY BUTTON MILD
-----------------------	--

Onset Date DD/MMM/YYYY	25 FEB 2014
---------------------------	-------------

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: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection	12 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	4
--------	---

Diagnosis Description	EYE GLASSES OR CONTACTS READING MILD
-----------------------	---

Onset Date DD/MMM/YYYY	UN UNK 1985
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection	12 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	5
--------	---

Diagnosis Description	THROAT NO TEETH MOST TEETH MISSING AND DECAYING UPPER AND LOWER MILD
-----------------------	---

Onset Date DD/MMM/YYYY	UN UNK 2000
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Medical History/Concomitant Disease (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:24

Generated On: 20 Jul 2016 21:44:07

Date of collection	12 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	6
--------	---

Diagnosis Description	BROKEN BONES RIGHT ANKLE BROKEN
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Onset Date DD/MMM/YYYY	UN UNK 2010
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 2010
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

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 12 MAR 2014
DD/MMM/YYYY

Time of assessment 10:50
hour:min 24-hour clock

Pulse rate 75
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 124
mmHg

Blood Pressure (diastolic) 80
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Physical Examination

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 12 MAR 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: 1233**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hcoleman1) 18 Jun 2015 21:18:00

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 29 Mar 2015 18:58:27

Generated On: 20 Jul 2016 21:44:07

Date	12 MAR 2014 DD/MMM/YYYY
------	----------------------------

Brand name	305 MENTHOL KINGS
------------	-------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Date of Assessment

12 MAR 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

10 to 19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

12 MAR 2014
DD/MMM/YYYY

Weight

086.6
kg

Height

188.5
cm

BMI (Derived)

24.4
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 18:58:20

Generated On: 20 Jul 2016 21:44:07

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 12 MAR 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 77
beats per minute

QRS Interval 93
msec

QT Interval 370
msec

QTcB Interval 419
msec

QTcF Interval 402
msec

PR Interval 157
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 18:58:20

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Spirometry (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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 12 MAR 2014
DD/MMM/YYYY

Time of assessment 11:20

Predicted FVC value 6.19
L

Best measured FVC value 6.54
L

Percent of predicted FVC value 106
%

Best measured FEV1 value 5.01
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Spirometry (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

Predicted FEV1 value	4.97 L
Percent of predicted FEV1 value	101 %
Calculated ratio between FEV1/FVC	0.77
MEF 25/75 value	4.19 L/s
Interpretation	Normal <input checked="" type="radio"/>
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: 1233**

Folder: Screening

Form: Spirometry (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

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

Date of assessment DD/MMM/YYYY 12 MAR 2014

Time of assessment 11:40

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 6.19 L

Best measured FVC value 6.32 L

Percent of predicted FVC value 102 %

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Spirometry (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

Best measured FEV1 value	5.06 L
--------------------------	-----------

Predicted FEV1 value	4.97 L
----------------------	-----------

Percent of predicted FEV1 value	102 %
---------------------------------	----------

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

MEF 25/75 value	4.72 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: 1233**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 MAR 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 18:58:23

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 18:58:23

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 29 Mar 2015 18:58:23

Generated On: 20 Jul 2016 21:44:07

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 29 Mar 2015 18:58:23

Generated On: 20 Jul 2016 21:44:07

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

If Not Done, please specify the reason: _____

Date of sample collection	12 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	10:19 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: 1233

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:23

Generated On: 20 Jul 2016 21:44:07

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 10:42
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 29 Mar 2015 18:58:22

Generated On: 20 Jul 2016 21:44:07

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	12 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	10:19 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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	12 MAR 2014
Subject Number	
Date of Birth	(b)
Gender	Male
Time of Sample Collection	11:32
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	90
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	12 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:32
Analyte Name	BUN
Code	001040
Result	9
Unit	MG/DL
Lower limit	6
Upper limit	20
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

CHOLESTEROL, TOTAL

Code

001065

Result

158

Unit

MG/DL

Lower limit

100

Upper limit

199

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

7.9

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

5.0

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

BILIRUBIN, TOTAL

Code

001099

Result

0.6

Unit

MG/DL

Lower limit

0.0

Upper limit

1.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

92

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

LDH

Code

001115

Result

137

Unit

IU/L

Lower limit

0

Upper limit

225

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

AST (SGOT)

Code

001123

Result

21

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	12 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:32
Analyte Name	TRIGLYCERIDES
Code	001172
Result	63
Unit	MG/DL
Lower limit	0
Upper limit	149
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	12 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:32
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	5.7
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	12 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:32
Analyte Name	SODIUM, SERUM
Code	001198
Result	143
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

BILIRUBIN, DIRECT

Code

001222

Result

0.20

Unit

MG/DL

Lower limit

0.00

Upper limit

0.40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

CREATININE, SERUM

Code

001370

Result

0.89

Unit

MG/DL

Lower limit

0.76

Upper limit

1.27

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

ALT (SGPT)

Code

001545

Result

15

Unit

IU/L

Lower limit

0

Upper limit

44

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

GGT

Code

001958

Result

9

Unit

IU/L

Lower limit

0

Upper limit

65

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:28

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:32

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:30

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	12 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:32
Analyte Name	WBC
Code	005025
Result	6.1
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

RBC

Code

005033

Result

5.33

Unit

X10E6/UL

Lower limit

4.14

Upper limit

5.80

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

HEMOGLOBIN

Code

005041

Result

16.9

Unit

G/DL

Lower limit

12.6

Upper limit

17.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

HEMATOCRIT

Code

005058

Result

48.5

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:32

Analyte Name

MCV

Code

015065

Result

91

Unit

FL

Lower limit

79

Upper limit

97

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

MCH

Code

015073

Result

31.7

Unit

PG

Lower limit

26.6

Upper limit

33.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

MCHC

Code

015081

Result

34.8

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

NEUTROPHILS

Code

015107

Result

59

Unit

%

Lower limit

40

Upper limit

74

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

MONOCYTES

Code

015131

Result

6

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type	HEMATOLOGY
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Date of Sample Collection YYYY/MM/DD	12 MAR 2014
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Subject Number	
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Date of Birth	(b) (6)
---------------	---------

Gender	Male <input checked="" type="radio"/>
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Time of Sample Collection	11:32
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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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

PLATELETS

Code

015172

Result

334

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

NEUTROPHILS (ABSOLUTE)

Code

015909

Result

3.6

Unit

X10E3/UL

Lower limit

1.4

Upper limit

7.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

LYMPHS (ABSOLUTE)

Code

015917

Result

1.9

Unit

X10E3/UL

Lower limit

0.7

Upper limit

3.1

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.4

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:32

Analyte Name

EOS (ABSOLUTE)

Code

015933

Result

0.2

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.4

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:32

Analyte Name

BASO (ABSOLUTE)

Code

015941

Result

0.0

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:31

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07157100040

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(12 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1

Unit

Lower limit

1.001

Upper limit

1.035

Flag

Low ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

PH

Code

13078

Result

8

Unit

Lower limit

5

Upper limit

8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

OCCULT BLOOD

Code

13102

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

12 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

10:25

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: 1233**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:34

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 21:44:07

Type	FTND
------	------

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

Date of assessment	2014 MAR 12
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	12:06
	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?	11-20 <input checked="" type="radio"/>
--	--

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	No <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: 1233**

Folder: Screening

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 29 Mar 2015 18:58:27

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 10:09
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? 1

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

Date of Visit

26 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 18:58:36

Generated On: 20 Jul 2016 21:44:07

*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: 1233

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:36

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:36

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:36

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:36

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

*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: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .
---------------------	--

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: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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

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

Result	NA
--------	----

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

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

Result	NA
--------	----

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

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 12:47
hour:min 24-hour clock

Pulse rate 83
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 113
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

Which Product Arm would you prefer to be randomized
to:

THS 2.2 menthol ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hcoleman1) 18 Jun 2015 21:18:01

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

Brand name

305 MENTHOL KINGS

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:00
hour:min 24-hour clock

Weight

87.4
kg

Waist circumference

94
cm

BMI

24.6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 29 Mar 2015 18:58:37

Generated On: 20 Jul 2016 21:44:07

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

If Not Done, please specify the reason: _____

Time of sample collection	11:59 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: 1233

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:37

Generated On: 20 Jul 2016 21:44:07

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 29 Mar 2015 18:58:37

Generated On: 20 Jul 2016 21:44:07

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:11
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 29 Mar 2015 18:58:35

Generated On: 20 Jul 2016 21:44:07

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	12:13
	hour:min 24-hour clock

Result	15
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Admission (Day -2)

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 26 MAR 2014
DD/MMM/YYYY

Time of assessment 12:27
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? 1

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Date of Visit

27 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 09:11
hour:min 24-hour clock

Pulse rate 84
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 115
mmHg

Blood Pressure (diastolic) 68
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 MAR 2014
---------------------	-------------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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	06:24
---	-------

Result(ppm)	11
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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	12:01
---	-------

Result(ppm)	28
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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	16:13
---	-------

Result(ppm)	35
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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	20:00
---	-------

Result(ppm)	39
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Start Time	10:04
	hour:min 24-hour clock

End Time	14:00
	hour:min 24-hour clock

Volume	914
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 27 DD/MMM/YYYY
Time of assessment	20:09 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	Moderately <input type="radio"/>
2. Did cigarettes taste good?	Moderately <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Very little <input type="radio"/>
4. Did smoking calm you down?	Moderately <input type="radio"/>
5. Did smoking make you feel more awake?	Little <input type="radio"/>
6. Did smoking make you feel less irritable?	Moderately <input type="radio"/>
7. Did smoking help you concentrate?	Moderately <input type="radio"/>
8. Did smoking reduce your hunger for food?	Little <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 18:58:38

Generated On: 20 Jul 2016 21:44:07

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? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:05 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: 1233**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
--	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 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 checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 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

19

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: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 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 checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 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

19

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: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 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 checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 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

19

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: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 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 checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 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

19

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

Less than 1 per day ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

8. On average, how many cigars do/did you smoke per day? Less than 1 per day ☒

Cigars
per day

8. On average, how many pipes do/did you smoke per day? Less than 1 per day ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 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 checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 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?

None ☒

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
--	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 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?

None ☒

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:03 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 checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	22 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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

0 Years

Months

02 Months

Days

60 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

Time

More than 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

None ☒

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

27 MAR 2014
DD/MMM/YYYY

Time of assessment

21:04

1. How long it takes for the subject to complete the SQ

3 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:04

1. How long it takes for the subject to complete the SQ 3 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: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:04

1. How long it takes for the subject to complete the SQ 3 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: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:04

1. How long it takes for the subject to complete the SQ 3 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: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:04

1. How long it takes for the subject to complete the SQ 3 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: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:04

1. How long it takes for the subject to complete the SQ 3 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:04

1. How long it takes for the subject to complete the SQ 3 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: 1233

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

Type	QSU
------	-----

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

Date of assessment	2014 MAR 27
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:07
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input type="radio"/>
-------------------	---------------------------------

1. I have a desire for a cigarette right now	Strongly disagree <input type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
---	--------------------------------

3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
---	--

4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly disagree <input type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly disagree <input type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 18:58:39

Generated On: 20 Jul 2016 21:44:07

7. A cigarette would taste good now Do not agree or disagree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112450002590
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	347
--------	-----

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	AA99128-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112450002590
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	50.4
--------	------

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	AA99128-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112450002590
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Analyte	HBMA
---------	------

Sample type	URINE
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Result	131
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Result Unit	NG/ML
-------------	-------

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	AA99128-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112460003087
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Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	236
--------	-----

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	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112460003087
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	15.5
--------	------

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	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112470001543
----------------	----------------

Analyte	HEMA
---------	------

Sample type	URINE
-------------	-------

Result	1.76
--------	------

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	AA99128-05
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:40

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112490001543
----------------	----------------

Analyte	3-OH BAP
---------	----------

Sample type	URINE
-------------	-------

Result	50.6
--------	------

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112510001565
----------------	----------------

Analyte	1-NA
---------	------

Sample type	URINE
-------------	-------

Result	41.8
--------	------

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-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112510001565
----------------	----------------

Analyte	2-NA
---------	------

Sample type	URINE
-------------	-------

Result	9.95
--------	------

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-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112510001565
----------------	----------------

Analyte	4-ABP
---------	-------

Sample type	URINE
-------------	-------

Result	7.08
--------	------

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-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112510001565
----------------	----------------

Analyte	O-TOL
---------	-------

Sample type	URINE
-------------	-------

Result	54.5
--------	------

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-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112530000491
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Analyte	11-DTXB2
---------	----------

Sample type	URINE
-------------	-------

Result	138
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112540000484
----------------	----------------

Analyte	IPF2A-III
---------	-----------

Sample type	URINE
-------------	-------

Result	92.7
--------	------

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	AA99128-12
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05115190003567
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Analyte	1-OHP
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Sample type	URINE
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Result	52.5
--------	------

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	AA99598-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05115170003565
----------------	----------------

Analyte	SBMA
---------	------

Sample type	URINE
-------------	-------

Result	0.948
--------	-------

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	AA99598-01
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05115170003565
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	1.79
--------	------

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	AA99598-01
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05115180003567
----------------	----------------

Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	1.76
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	
--------------	--

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:41

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05115160001543
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	36.6
--------	------

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Date of Visit

28 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 09:04
hour:min 24-hour clock

Pulse rate 87
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 111
mmHg

Blood Pressure (diastolic) 70
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

Date DD/MMM/YYYY	
---------------------	--

Time hour:min 24-hour clock	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

Date DD/MMM/YYYY	
---------------------	--

Time hour:min 24-hour clock	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

Date DD/MMM/YYYY	
---------------------	--

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

Date DD/MMM/YYYY	
---------------------	--

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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	28 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	05:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

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	08:40
---	-------

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

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: 1233**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

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: 1233**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT IS AN EARLY TERM
---	--------------------------

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: 1233

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

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

28 MAR 2014

05:15

trans-3'-hydroxyc
otinine

28 MAR 2014

05:15

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 29 Mar 2015 18:58:55

Generated On: 20 Jul 2016 21:44:07

Time of caffeine tablet intake

Sample collection Not Done

True

If Not Done, please specify the reason:

THE SUBJECT IS AN EARLY TERM AND DISCHARGED FROM
THE UNIT

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

Caffeine

Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	05:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Start Date

Start Time

End Date

End Time

Volume

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Were samples for 24h collected?

No ☒

If No, please specify the reason:

THE SUBJECT IS AN EARLY
TERM AND DISCHARGED
FROM THE UNIT

How many primary tubes were collected? _____

How many back up tubes were collected? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

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

Date of assessment DD/MMM/YYYY	2014 MAR 28 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:07 hour:min 24-hour clock
--------------------	---------------------------------

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

2. Anxious, nervous

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?	Slight <input type="radio"/>
---	------------------------------

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 18:58:42

Generated On: 20 Jul 2016 21:44:07

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 28 DD/MMM/YYYY
Time of assessment	06:04 hour:min 24-hour clock
Assessment Status	Completed <input checked="" type="radio"/>
Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	No <input checked="" type="radio"/>
If YES, please answer the following questions:	
First Question: Cough Impact Scale How much is your cough bothering you?	-9
Second Question: Cough Intensity Scale: How intense is your cough?	Not Applicable <input checked="" type="radio"/>
Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Not Applicable <input checked="" type="radio"/>
Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	Not Applicable <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:15
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: 1233**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

05:15
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: 1233**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

No ☒

Time of Buccal Collection

Time of Nasal Epithelial Collection

Was the subject fasting for at least 30 minutes at time of
sample collection?

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	103
Reported Numeric Result	103
Reference Range low	50
Reference Range high	321
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	99
Reported Numeric Result	99
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	156
Reported Numeric Result	156
Reference Range low	150
Reference Range high	264
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)


Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	87
Reported Numeric Result	87
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	120
Reported Numeric Result	120
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	138
Reported Numeric Result	138
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.3
Reported Numeric Result	4.3
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:15
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT29
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:15
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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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	CREATININE (RATE BLANKED)
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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	1.0
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Reported Numeric Result	1.0
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Reference Range low	0.5
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Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

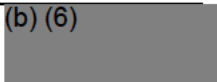
Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:15
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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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.48
Reported Numeric Result	0.48
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT100

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	31
Reported Numeric Result	31
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:15
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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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)


Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT11

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.24
Reported Numeric Result	0.24
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.04
Reported Numeric Result	0.04
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:15
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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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	340
Reported Numeric Result	340
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

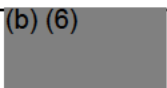
Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	54.8
Reported Numeric Result	54.8
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34.1
Reported Numeric Result	34.1
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT17

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.1
Reported Numeric Result	7.1
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT18

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:15
------------------------	-------

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715921
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	51
Reported Numeric Result	51
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	93
Reported Numeric Result	93
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT40

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	17.1
Reported Numeric Result	17.1
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.79
Reported Numeric Result	6.79
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT71

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45


Generated On: 20 Jul 2016 21:44:07

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	3.72
Reported Numeric Result	3.72
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.32
Reported Numeric Result	2.32
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45


Generated On: 20 Jul 2016 21:44:07

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

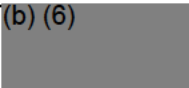
Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.013
Reported Numeric Result	1.013
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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)


Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

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: 1233

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45


Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

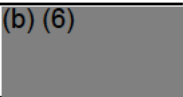
Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45


Generated On: 20 Jul 2016 21:44:07

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

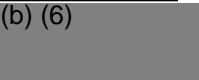
Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45


Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715921

Actual Collection Date 2014 03 28

Actual Collection Time 05:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45


Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 18:58:45

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 21:44:07

Sample Accession number	3271592139
-------------------------	------------

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: 1233

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	No <input checked="" type="radio"/>
-------------------------------	-------------------------------------

Reason not done	SUBJECT IS AN EARLY TERM
-----------------	--------------------------

Date of assessment	_____
--------------------	-------

Time of assessment	_____
--------------------	-------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device. _____

If you agree or strongly agree, please describe : _____

2. You enjoy smoking with the device as much as without it. _____

If you disagree or strongly disagree, please describe : _____

3. The taste of the conventional cigarettes/products is different with the device. _____

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 18:58:56

Generated On: 20 Jul 2016 21:44:07

4. The device is easy to use. _____

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device. _____

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.5

Reported Numeric Result

5.5

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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43


Generated On: 20 Jul 2016 21:44:07

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

58

Reported Numeric Result

58

Reference Range low

28

Reference Range high

63

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.066
Reported Numeric Result	0.066
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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	APOLIPOPROTEIN A1, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	158
Reported Numeric Result	158
Reference Range low	110
Reference Range high	205
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	65
Reported Numeric Result	65
Reference Range low	55
Reference Range high	140
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	294
Reported Numeric Result	294
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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.96
Reported Numeric Result	14.96
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: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

SI Numeric Result


SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High 

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	254.4
Reported Numeric Result	254.4
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1233
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715921
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	83
----------------------	----

Reported Numeric Result	83
-------------------------	----

Reference Range low	78
---------------------	----

Reference Range high	185
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:43

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112520000424
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	265
--------	-----

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-MAR-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

Sample Barcode	05112520000424
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	28.7
--------	------

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	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of Visit	28 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	09:35 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	No <input checked="" type="radio"/>
---	-------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 21:18:03

Generated On: 20 Jul 2016 21:44:07

Were Vitals Signs assessed? _____

If No, please specify the reason: _____

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 _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

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 REQUIRED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

28 MAR 2014
DD/MMM/YYYY

Time of assessment

09:24
hour:min 24-hour clock

Weight

86.8
kg

BMI

24.4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 83
beats per minute

QRS Interval 93
msec

QT Interval 369
msec

QTcB Interval 435
msec

PR Interval 150
msec

QTcF Interval 412
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 18:58:57

Generated On: 20 Jul 2016 21:44:07

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DISCONTINUED
FROM ENROLLMENT

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

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DISCONTINUED
FROM ENROLLMENT

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

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

Were samples collected?

No ☒

If No, please specify the reason:

TWO SAMPLES WERE
COLLECTED ON THIS DATE
ONE FOR DAY 0 OBTAINED AT
0515 AND ONE WITH EARLY
TERM PROCEDURES THE
SPECIMEN COLLECTED FOR
DAY 0 WAS SENT FOR
PROCESSING

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hcoleman1) 18 Jun 2015 21:18:02

Generated On: 20 Jul 2016 21:44:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT DISCONTINUED FROM ENROLLMENT
---	---

Actual Time of Assessment	<hr/>
---------------------------	-------

Result	<hr/>
--------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

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: 1233

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	06:25
----------------------	-------

Time of butt return	06:32
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	06:59
----------------------	-------

Time of butt return	07:07
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	07:14
----------------------	-------

Time of butt return	07:22
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	08:34
----------------------	-------

Time of butt return	08:42
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	09:24
----------------------	-------

Time of butt return	09:30
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	11:14
----------------------	-------

Time of butt return	11:23
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	12:04
----------------------	-------

Time of butt return	12:12
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	12:50
----------------------	-------

Time of butt return	12:57
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	14:01
----------------------	-------

Time of butt return	14:08
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	14:38
----------------------	-------

Time of butt return	14:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	15:33
----------------------	-------

Time of butt return	15:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	16:20
----------------------	-------

Time of butt return	16:28
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	17:22
----------------------	-------

Time of butt return	17:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	18:08
----------------------	-------

Time of butt return	18:15
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	18:55
----------------------	-------

Time of butt return	19:02
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	19:43
----------------------	-------

Time of butt return	19:50
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	20:18
----------------------	-------

Time of butt return	20:25
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	21:48
----------------------	-------

Time of butt return	21:56
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	22:26
----------------------	-------

Time of butt return	22:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

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: 1233

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	22:46
----------------------	-------

Time of butt return	22:54
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 1233**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	08:41
----------------------	-------

Time of butt return	08:46
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	094
---------------------	-----

SODIM sample holder number	0263
----------------------------	------

SODIM file number	VAL10094ZRHXX1064001
-------------------	----------------------

Comment	
---------	--

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: 1233

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 29 Mar 2015 18:58:58

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	09:06
----------------------	-------

Time of butt return	09:13
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	094
---------------------	-----

SODIM sample holder number	0263
----------------------------	------

SODIM file number	VAL10094ZRHXX1064002
-------------------	----------------------

Comment	
---------	--

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: 1233**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

Date of product use DD/MMM/YYYY	26 MAR 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

Time of distribution	15:21
----------------------	-------

Time of product return	<input type="text"/>
------------------------	----------------------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

Tobacco plug kit number	<input type="text"/>
-------------------------	----------------------

Tobacco plug vial number	<input type="text"/>
--------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 21:44:07

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: 1233**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 21:44:07

SODIM file number	VAL10094ZRHXX1064001
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File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
----------	---

Comment	<hr/>
---------	-------

Modified File Number	VALI0094ZRHXX1064001
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 21:44:07

SODIM file number	VAL10094ZRHXX1064002
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File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
---------------------------------	-------------

Operator	Anthony Bruchet <input checked="" type="radio"/>
----------	--

Comment	<hr/>
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Modified File Number	VALI0094ZRHXX1064002
----------------------	----------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:03

Generated On: 20 Jul 2016 21:44:07

AE Identifier	1
---------------	---

Adverse Event	SYNCPAL EPISODE
---------------	-----------------

Start Date	28 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	28 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input checked="" type="radio"/>
--------------------------	-------------------------------------

Severity	Severe 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	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: 1233**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:03

Generated On: 20 Jul 2016 21:44:07

Action taken with study product

Product use Interrupted ☒

Other action taken

VITAL SIGNS, BLOOD SUGAR
AND O2 SATURATION
SUBJECT DISCONTINUED
FROM STUDY

Outcome

Recovered or Resolved ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

Has the subject taken previous or concomitant
medication?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp CHEMISTRY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp CHEMISTRY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

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

Date of Sample Collection YYYY/MM/DD	14 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	08:41
---------------------------	-------

Analyte Name	POTASSIUM, SERUM
--------------	------------------

Code	001180
------	--------

Result	4.2
--------	-----

Unit	MMOL/L
------	--------

Lower limit	3.5
-------------	-----

Upper limit	5.2
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp CHEMISTRY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100010

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1233

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 18:59:00

Generated On: 20 Jul 2016 21:44:07

Date of Sample Collection
DD/MMM/YYYY

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

14 MAR 2014

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 21:17:57

Generated On: 20 Jul 2016 21:44:07

End of study date

25 APR 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Adverse Events ☒

Details:

P.I DISCRETION DUE TO
SYNCOPAL EPISODE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1233**

Form: Consent Withdrawal

Data signed: (hfarmer1) 29 Mar 2015 18:58:20

Generated On: 20 Jul 2016 21:44:07

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