

Subject Case Report Forms

1098 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 13:21:07

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Form: Subject

Data signed: (hfarmer1) 26 Mar 2015 14:41:00

Generated On: 20 Jul 2016 13:21:07

Screening number	1098
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

30 JAN 2014
DD/MMM/YYYY

Randomization Date

Randomization Time

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Date of Visit

21 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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

Yes ☒

Consent Date

21 JAN 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

21 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

*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: 1098**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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.
---------------------	---

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: 1098**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Inclusion Criterion Number	2
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Inclusion Criterion	Subject is at a minimum 22 years of age(inclusive).	<input checked="" type="radio"/>
---------------------	--	----------------------------------

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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

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: 1098**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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.
---------------------	--

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: 1098**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

*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: 1098**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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
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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: 1098

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

Exclusion Criterion Number	3
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Exclusion Criterion	The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.
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Result	No <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: 1098**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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

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: 1098

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

Exclusion Criterion Number	7
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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.
---------------------	--

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: 1098

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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
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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: 1098

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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.
---------------------	---

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: 1098**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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

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: 1098**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

Exclusion Criterion Number	16
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Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.
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Result	No
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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: 1098**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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

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

Result	No <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: 1098**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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

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

Result	No
--------	----

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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.
---------------------	--

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: 1098**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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.	<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: 1098**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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

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

Result	No
--------	----

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

Date of Birth

x

Sex

Female ☒

Race

White ☒

Other, specify

Ethnicity

Not Hispanic ☒

Date the Subject signed the Informed Consent

21 JAN 2014
DD/MMM/YYYY

Time the Subject signed the Informed Consent

10:42
hour:min 24-hour clock

Age(Derived)

51

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection

21 JAN 2014
DD/MMM/YYYY

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	1
--------	---

Diagnosis Description	BREAST REDUCTION SURGERY
-----------------------	-----------------------------

Onset Date DD/MMM/YYYY	UN UNK 2008
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 2008
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	2
--------	---

Diagnosis Description	CHOLECYSTECTOMY
-----------------------	-----------------

Onset Date DD/MMM/YYYY	UN UNK 2008
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 2008
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection	21 JAN 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

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

Diagnosis Description	NORMAL VAGINAL DELIVERY
-----------------------	-------------------------

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

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

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection

21 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

4

Diagnosis Description

NORMAL VAGINAL DELIVERY

Onset Date
DD/MMM/YYYY

(b) (6)

Stop Date
DD/MMM/YYYY

(b) (6)

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	SCREW AND IMPLANTED DISC
-----------------------	--------------------------

Onset Date DD/MMM/YYYY	UN UNK 2005
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 2005
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Medical History/Concomitant Disease (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Date of collection	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	BACK PAIN
-----------------------	-----------

Onset Date DD/MMM/YYYY	UN UNK 2005
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 2005
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

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

21 JAN 2014
DD/MMM/YYYY

Time of assessment

12:02
hour:min 24-hour clock

Pulse rate

78
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

135
mmHg

Blood Pressure (diastolic)

89
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 JAN 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Date	21 JAN 2014 DD/MMM/YYYY
------	----------------------------

Brand name	MISTY MENTHOL GREEN 120'S
------------	------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Date of Assessment

21 JAN 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

10 to 19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 JAN 2014
DD/MMM/YYYY

Weight

80.3
kg

Height

157
cm

BMI (Derived)

32.6
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment:

21 JAN 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

83
beats per minute

QRS Interval

84
msec

QT Interval

398
msec

QTcB Interval

468
msec

QTcF Interval

443
msec

PR Interval

168
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

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 21 JAN 2014
DD/MMM/YYYY

Time of assessment 12:55

Predicted FVC value 3.26
L

Best measured FVC value 2.71
L

Percent of predicted FVC value 83
%

Best measured FEV1 value 2.22
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Predicted FEV1 value	2.58 L
----------------------	-----------

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

Calculated ratio between FEV1/FVC	0.82
-----------------------------------	------

MEF 25/75 value	2.38 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: 1098**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

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 21 JAN 2014
DD/MMM/YYYY

Time of assessment 13:25

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 3.26
L

Best measured FVC value 2.77
L

Percent of predicted FVC value 85
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:03

Generated On: 20 Jul 2016 13:21:07

Best measured FEV1 value	2.27 L
Predicted FEV1 value	2.58 L
Percent of predicted FEV1 value	88 %
Calculated ratio between FEV1/FVC	0.82
MEF 25/75 value	2.48 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: 1098**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, please specify the reason: _____

Date of sample collection	21 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	11:15 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: 1098

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 11:54
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 13:21:07

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

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

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

Date of Test	21 JAN 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	11:38 hour:min 24-hour clock
--------------	---------------------------------

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 26 Mar 2015 14:41:02

Generated On: 20 Jul 2016 13:21:07

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	21 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	11:15 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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	88
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

BUN

Code

001040

Result

10

Unit

MG/DL

Lower limit

6

Upper limit

24

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

CHOLESTEROL, TOTAL

Code

001065

Result

192

Unit

MG/DL

Lower limit

100

Upper limit

199

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

7.2

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	ALBUMIN, SERUM
Code	001081
Result	4.6
Unit	G/DL
Lower limit	3.5
Upper limit	5.5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

BILIRUBIN, TOTAL

Code

001099

Result

0.5

Unit

MG/DL

Lower limit

0.0

Upper limit

1.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

84

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

LDH

Code

001115

Result

188

Unit

IU/L

Lower limit

0

Upper limit

214

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	AST (SGOT)
Code	001123
Result	27
Unit	IU/L
Lower limit	0
Upper limit	40
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	TRIGLYCERIDES
Code	001172
Result	159
Unit	MG/DL
Lower limit	0
Upper limit	149
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

SODIUM, SERUM

Code

001198

Result

140

Unit

MMOL/L

Lower limit

134

Upper limit

144

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	BILIRUBIN, DIRECT
Code	001222
Result	0.10
Unit	MG/DL
Lower limit	0.00
Upper limit	0.40
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.69
Unit	MG/DL
Lower limit	0.57
Upper limit	1.00
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

ALT (SGPT)

Code

001545

Result

39

Unit

IU/L

Lower limit

0

Upper limit

32

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

GGT

Code

001958

Result

18

Unit

IU/L

Lower limit

0

Upper limit

60

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

WBC

Code

005025

Result

9.9

Unit

X10E3/UL

Lower limit

3.4

Upper limit

10.8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(21 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

RBC

Code

005033

Result

4.84

Unit

X10E6/UL

Lower limit

3.77

Upper limit

5.28

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

HEMOGLOBIN

Code

005041

Result

14.9

Unit

G/DL

Lower limit

11.1

Upper limit

15.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

HEMATOCRIT

Code

005058

Result

43.1

Unit

%

Lower limit

34.0

Upper limit

46.6

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	MCV
Code	015065
Result	89
Unit	FL
Lower limit	79
Upper limit	97
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

Analyte Name

MCH

Code

015073

Result

30.8

Unit

PG

Lower limit

26.6

Upper limit

33.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female

Time of Sample Collection

12:44

Analyte Name

MCHC

Code

015081

Result

34.6

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

NEUTROPHILS

Code

015107

Result

62

Unit

%

Lower limit

40

Upper limit

74

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

LYMPHS

Code

015123

Result

29

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	MONOCYTES
Code	015131
Result	7
Unit	%
Lower limit	4
Upper limit	12
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	EOS
Code	015149
Result	2
Unit	%
Lower limit	0
Upper limit	5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

BASOS

Code

015156

Result

0

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

PLATELETS

Code

015172

Result

360

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	6.1
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

LYMPHS (ABSOLUTE)

Code

015917

Result

2.9

Unit

X10E3/UL

Lower limit

0.7

Upper limit

3.1

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female



Time of Sample Collection

12:44

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.7

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 JAN 2014
Subject Number	
Date of Birth	x
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:44
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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

12:44

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:05

Generated On: 20 Jul 2016 13:21:07

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02157100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(21 JAN 2014)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(21 JAN 2014)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1.005

Unit

Lower limit

1.001

Upper limit

1.035

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(21 JAN 2014)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

Analyte Name

PH

Code

13078

Result

6

Unit

Lower limit

5

Upper limit

8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

Analyte Name

OCCULT BLOOD

Code

13102

Result

50

Unit

Lower limit

NEGATIVE

Upper limit

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

Analyte Name

BILIRUBIN

Code

13104

Result

+

Unit

Lower limit

NEGATIVE

Upper limit

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 JAN 2014

Subject Number

Date of Birth

x

Gender

Female ☒

Time of Sample Collection

11:35

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: 1098**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 13:21:07

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

Date of Birth	x
---------------	---

Date of assessment	2014 JAN 21
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	13:49
	hour:min 24-hour clock

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

1. How soon after you wake up do you smoke your first cigarette?	6-30 minutes <input checked="" type="radio"/>
--	---

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input checked="" type="radio"/>
--	-------------------------------------

3. Which cigarette would you hate most to give up?	The first in the morning <input checked="" type="radio"/>
--	---

4. How many cigarettes per day do you smoke?	11-20 <input checked="" type="radio"/>
--	--

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	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: 1098**

Folder: Screening

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:04

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 11:02
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 0

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Date of Visit

28 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

*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: 1098

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

*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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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 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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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.	<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: 1098**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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	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: 1098**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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 13:33
hour:min 24-hour clock

Pulse rate 93
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 140
mmHg

Blood Pressure (diastolic) 91
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Which Product Arm would you prefer to be randomized
to:

mCC 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Brand name

MISTY MENTHOL GREEN
120'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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? 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: 1098**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:55
hour:min 24-hour clock

Weight

80.5
kg

Waist circumference

42
cm

BMI

32.7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, please specify the reason: _____

Time of sample collection	14:46 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: 1098

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 15:17
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 13:21:07

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

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

Time of Test	14:49
	hour:min 24-hour clock

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

If unclear, please confirm with FSH test

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 14:41:07

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	13:23
	hour:min 24-hour clock

Result	15
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 28 JAN 2014
DD/MMM/YYYY

Time of assessment 13:45
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 0

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Date of Visit

29 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

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

10:06
hour:min 24-hour clock

Pulse rate

93
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

147
mmHg

Blood Pressure (diastolic)

98
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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	06:36
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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	12:12
---	-------

Result(ppm)	20
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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	16:15
---	-------

Result(ppm)	24
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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	20:39
---	-------

Result(ppm)	23
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Start Time	10:12
	hour:min 24-hour clock

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

Volume	504
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Date of Birth

x

Date of assessment

2014 JAN 29
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:23
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Moderately ☒

4. Did smoking calm you down?

Not at all ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

Little ☒

8. Did smoking reduce your hunger for food?

Little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

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? Quite a lot ☐

12. Did you enjoy smoking? A lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

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

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:26 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: 1098**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

Reason not done	
-----------------	--

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

Reason not done	
-----------------	--

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	Currently (last 3 months) <input checked="" type="radio"/>
------	--

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

Manufactured Cigarettes per day	10
---------------------------------	----

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?	None <input checked="" type="radio"/>
--	---------------------------------------

Hand-rolled Cigarettes per day	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

Reason not done	
-----------------	--

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	1 year ago <input checked="" type="radio"/>
------	---

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

Manufactured Cigarettes per day	10
---------------------------------	----

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?	None <input checked="" type="radio"/>
--	---------------------------------------

Hand-rolled Cigarettes per day	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

Reason not done	
-----------------	--

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	5 years ago <input checked="" type="radio"/>
------	--

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

Manufactured Cigarettes per day	10
---------------------------------	----

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?	None <input checked="" type="radio"/>
--	---------------------------------------

Hand-rolled Cigarettes per day	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

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

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	10 years ago <input checked="" type="radio"/>
------	---

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

Manufactured Cigarettes per day	10
---------------------------------	----

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?	None <input checked="" type="radio"/>
--	---------------------------------------

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

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

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	15 years ago <input checked="" type="radio"/>
------	---

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

Manufactured Cigarettes per day	8
---------------------------------	---

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: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

Reason not done	
-----------------	--

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	20 years ago <input checked="" type="radio"/>
------	---

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

Manufactured Cigarettes per day	8
---------------------------------	---

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: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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

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

Reason not done	
-----------------	--

Date of assessment	29 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:33 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	00 Years
-------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

Months	00 Months
--------	-----------

Days	00 Days
------	---------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	00 Years
-------	----------

Months	00 Months
--------	-----------

Days	00 Days
------	---------

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MISTY MENTHOL GREEN 120'S

Time	More than 20 years ago <input checked="" type="radio"/>
------	---

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

Manufactured Cigarettes per day	6
---------------------------------	---

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: 1098**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:09

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 minutes

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 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: 1098

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 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: 1098**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 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: 1098

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 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: 1098

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 29 JAN 2014
DD/MMM/YYYY

Time of assessment 20:35

1. How long it takes for the subject to complete the SQ 05 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: 1098

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

Type	QSU
Date of Birth	x
Date of assessment	2014 JAN 29
DD/MMM/YYYY	
Time of assessment	20:20
hour:min 24-hour clock	
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Somewhat disagree <input type="radio"/>
5. All I want right now is a cigarette	Somewhat disagree <input type="radio"/>
6. I have an urge for a cigarette	Somewhat disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:41:11

Generated On: 20 Jul 2016 13:21:07

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 Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112450000232
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112450000232
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112450000232
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Analyte	HBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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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
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Date of Collection	2014-JAN-29
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112460000931
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112460000931
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112470000232
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Analyte	HEMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-05
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Date of Collection	2014-JAN-29
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112490000232
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JAN-29
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112510000232
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112510000232
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112510000232
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112510000232
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112530000141
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-11
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Date of Collection	2014-JAN-29
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112540000148
Analyte	IPF2A-III
Sample type	URINE
Result	55.1
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-12
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05115190000100
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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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	AA99598-03
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Date of Collection	2014-JAN-29
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05115170001200
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-01
Date of Collection	2014-JAN-29
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05115170001200
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

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

Celerion Study Number	AA99598-01
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Date of Collection	2014-JAN-29
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:12

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05115180001189
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-JAN-29
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05115160000221
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Analyte	CREATININE
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Sample type	URINE
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Result	.
--------	---

Result Unit	MG/DL
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-14
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Date of Collection	2014-JAN-29
--------------------	-------------

Timepoint-minutes	_____
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Urine Start Day	_____
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:13

Generated On: 20 Jul 2016 13:21:07

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Date of Visit

30 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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 10:08
hour:min 24-hour clock

Pulse rate 93
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 156
mmHg

Blood Pressure (diastolic) 98
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:41:15

Generated On: 20 Jul 2016 13:21:07

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT IS AN EARLY
TERMINATION

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT IS AN EARLY
TERMINATION

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT HAS BEEN DISCHARGED FROM UNIT
---	--

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	<hr/>
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 14:41:15

Generated On: 20 Jul 2016 13:21:07

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	30 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

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	08:36
---	-------

Result(ppm)	8
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT IS DISCHARGED FROM UNIT
---	------------------------------------

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: 1098**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT IS DISCHARGED FROM UNIT
---	------------------------------------

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: 1098**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT IS DISCHARGED FROM UNIT
---	------------------------------------

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: 1098

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 14:41:14

Generated On: 20 Jul 2016 13:21:07

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

30 JAN 2014

06:26

trans-3'-hydroxyc
otinine

30 JAN 2014

06:26

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 14:41:15

Generated On: 20 Jul 2016 13:21:07

Time of caffeine tablet intake

Sample collection Not Done

True

If Not Done, please specify the reason:

SUBJECT IS AN EARLY TERMINATION

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: 1098**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 26 Mar 2015 14:41:15

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

Start Date	30 JAN 2014 DD/MMM/YYYY
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Start Time	06:21 hour:min 24-hour clock
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End Date	30 JAN 2014 DD/MMM/YYYY
----------	----------------------------

End Time	10:28 hour:min 24-hour clock
----------	---------------------------------

Volume	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT IS AN EARLY
TERMINATION

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Date of Birth

x

Date of assessment
DD/MMM/YYYY

2014 JAN 30
DD/MMM/YYYY

Time of assessment

06:08
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Date of Birth

x

Date of assessment
DD/MMM/YYYY

2014 JAN 30
DD/MMM/YYYY

Time of assessment

06:05
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

42

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Sometimes ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:26
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: 1098**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:26
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: 1098**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1029
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Battery Name	TRIGLYCERIDES
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Lab Test ID	RCT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	203
Reported Numeric Result	203
Reference Range low	52
Reference Range high	262
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☐

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	106
Reported Numeric Result	106
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	176
Reported Numeric Result	176
Reference Range low	171
Reference Range high	291
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☐

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☐

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.9
Reported Numeric Result	6.9
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☒

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.9
Reported Numeric Result	3.9
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth x

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	74
Reported Numeric Result	74
Reference Range low	35
Reference Range high	123
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth x

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	157
Reported Numeric Result	157
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☒

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> X
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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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	RCT16
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.5
Reported Numeric Result	3.5
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16


Generated On: 20 Jul 2016 13:21:07

Lab Test Name

DIRECT BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

<0.1

Reported Numeric Result

Reference Range low

0.0

Reference Range high

0.4

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.4
Reference Range high	1.1
Range Units	MG/DL
Conventional Text Result	
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☒

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	53
Reported Numeric Result	53
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	24
Reported Numeric Result	24
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" 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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.36
Reported Numeric Result	0.36
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	30
Reported Numeric Result	30
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
-----------------------	--------------------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.25
Reported Numeric Result	0.25
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
-----------------------	--------------------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	378
Reported Numeric Result	378
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	61.1
Reported Numeric Result	61.1
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	29.9
Reported Numeric Result	29.9
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	5.1
Reported Numeric Result	5.1
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	40
Reported Numeric Result	40
Reference Range low	34
Reference Range high	48
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> <div>x</div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.5
Reported Numeric Result	4.5
Reference Range low	4.1
Reference Range high	5.6
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	90
Reported Numeric Result	90
Reference Range low	79
Reference Range high	98
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> x
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.6
Reported Numeric Result	13.6
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☒

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.17
Reported Numeric Result	7.17
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☒

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

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: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16


Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth x

Visit Name

Visit Type Scheduled ☒

Accession ID V225553

Actual Collection Date 2014 01 30

Actual Collection Time 06:26

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.38
Reported Numeric Result	4.38
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	<hr/> X
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225553
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Actual Collection Date	2014 01 30
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Actual Collection Time	06:26
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.14
Reported Numeric Result	2.14
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/> x
-----------------------	----------------------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT10
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/>
-----------------------	-------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	1.019
Reported Numeric Result	1.019
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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/> x
-----------------------	----------------------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/> x
-----------------------	----------------------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16


Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/> x
-----------------------	----------------------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16


Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/> x
-----------------------	----------------------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16


Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	<hr/>
-----------------------	-------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16


Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 13:21:07

Sample Accession number	3122555339
-------------------------	------------

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: 1098

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT IS AN EARLY TERMINATION
-----------------	------------------------------------

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: 1098**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:41:16

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	444
Reported Numeric Result	444
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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.42
Reported Numeric Result	7.42
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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	219.8
Reported Numeric Result	219.8
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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.7

Reported Numeric Result

5.7

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	41
Reported Numeric Result	41
Reference Range low	37
Reference Range high	92
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
---------------	-----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	1.500
----------------------	-------

Reported Numeric Result	1.500
-------------------------	-------

Reference Range low	<hr/>
---------------------	-------

Reference Range high	<=0.287
----------------------	---------

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/>
--------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

SI Text Result

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	APOLIPOPROTEIN A1, RAND
---------------	-------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	119
----------------------	-----

Reported Numeric Result	119
-------------------------	-----

Reference Range low	125
---------------------	-----

Reference Range high	215
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	99
Reported Numeric Result	99
Reference Range low	55
Reference Range high	125
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1098
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	x
-----------------------	------------------------------------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225553
--------------	---------

Actual Collection Date	2014 01 30
------------------------	------------

Actual Collection Time	06:26
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	118
----------------------	-----

Reported Numeric Result	118
-------------------------	-----

Reference Range low	90
---------------------	----

Reference Range high	215
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:28

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 13:21:07

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112520000064
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-JAN-30
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 13:21:07

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 13:21:07

Sample Barcode	05112520000064
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-JAN-30
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 13:21:07

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hcoleman1) 18 Jun 2015 20:15:12

Generated On: 20 Jul 2016 13:21:07

Date of Visit

30 JAN 2014
DD/MMM/YYYY

Discharge Time

11:37
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hcoleman1) 18 Jun 2015 20:15:12

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hcoleman1) 18 Jun 2015 20:15:11

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 89
beats per minute

QRS Interval 86
msec

QT Interval 357
msec

QTcB Interval 437
msec

PR Interval 154
msec

QTcF Interval 408
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hcoleman1) 18 Jun 2015 20:15:10

Generated On: 20 Jul 2016 13:21:07

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Discharge (Confinement)

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 13:21:07

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

If Not Done, specify reason

Time of Test	12:14
	hour:min 24-hour clock

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

If unclear, please confirm with FSH test

Specify result of FSH test

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	06:37
----------------------	-------

Time of butt return	06:49
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	08:28
----------------------	-------

Time of butt return	08:38
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	09:31
----------------------	-------

Time of butt return	09:42
---------------------	-------

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: 1098

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	10:32
----------------------	-------

Time of butt return	10:44
---------------------	-------

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: 1098

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	13:25
----------------------	-------

Time of butt return	13:35
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	15:29
----------------------	-------

Time of butt return	15:39
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	18:04
----------------------	-------

Time of butt return	18:13
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	19:36
----------------------	-------

Time of butt return	19:47
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	21:08
----------------------	-------

Time of butt return	21:17
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	29 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	21:54
----------------------	-------

Time of butt return	22:06
---------------------	-------

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: 1098**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	08:38
----------------------	-------

Time of butt return	08:47
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	True
--------------------	------

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: 1098

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 26 Mar 2015 14:41:30

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	30 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	09:36
----------------------	-------

Time of butt return	09:45
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	True
--------------------	------

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: 1098**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 26 Mar 2015 14:41:31

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:31

Generated On: 20 Jul 2016 13:21:07

Date of product use DD/MMM/YYYY	28 JAN 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

Time of distribution	18:38
----------------------	-------

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: 1098

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 14:41:31

Generated On: 20 Jul 2016 13:21:07

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: 1098**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 26 Mar 2015 14:41:32

Generated On: 20 Jul 2016 13:21:07

Was there any Adverse Event for this subject?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 20:15:12

Generated On: 20 Jul 2016 13:21:07

AE Identifier	1
---------------	---

Adverse Event	HEADACHE
---------------	----------

Start Date	29 JAN 2014
------------	-------------

DD/MMM/YYYY

End Date	30 JAN 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 20:15:12

Generated On: 20 Jul 2016 13:21:07

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 20:15:12

Generated On: 20 Jul 2016 13:21:07

AE Identifier	2
---------------	---

Adverse Event	ELEVATED BLOOD PRESSURE
---------------	-------------------------

Start Date	30 JAN 2014
------------	-------------

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact	Yes <input type="radio"/>
--------------------------	---------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 20:15:12

Generated On: 20 Jul 2016 13:21:07

Action taken with study product

Not Applicable ☒

Other action taken

SUBJECT DISCONTINUED
FROM STUDY

Outcome

Unknown ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 26 Mar 2015 14:41:32

Generated On: 20 Jul 2016 13:21:07

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1098

Folder: Unscheduled Visit

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:41:32

Generated On: 20 Jul 2016 13:21:07

Date of assessment DD/MMM/YYYY	Time of assessment hour:min 24-hour clock	Has the subject smoked within 15 minutes prior to assessm ent	Pulse rate beats per minute	Respiratory rate breaths per minute	Blood Pressure (systolic) mmHg	Blood Pressure (diastolic) mmHg	Vital Signs Position of Subject
28 JAN 2014	13:35	No	93		143	93	Supine
29 JAN 2014	10:07	No	90		147	96	Supine
30 JAN 2014	10:10	No			156	94	Supine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 20:15:09

Generated On: 20 Jul 2016 13:21:07

End of study date

27 FEB 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Adverse Events ☒

Details:

EARLY TERMINATION DUE TO
ELEVATED BLOOD PRESSURE.
PI ADVISED SUBJECT TO
FOLLOWUP WITH THEIR PCP.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1098**

Form: Consent Withdrawal

Data signed: (hfarmer1) 26 Mar 2015 14:41:01

Generated On: 20 Jul 2016 13:21:07

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