

Subject Case Report Forms

0064 (Prod: Osaki Hospital Tokyo heart center)

Generated On: 17 Jul 2016 22:26:21

All time stamps listed in this document are displayed in GMT

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Form: Subject

Data signed: (Heart1) 29 Oct 2014 03:06:04

Generated On: 17 Jul 2016 22:26:21

Screening number	0064
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Site number	TOK
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Subject Status

Form: Subject Status

Data signed: (Heart1) 29 Oct 2014 03:06:04

Generated On: 17 Jul 2016 22:26:21

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

21 SEP 2013
DD/MMM/YYYY

Randomization Time

11:33
hour:min 24-hour clock

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Date of Visit

29 AUG 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Additional Informed Consent

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

Yes ☒

Consent Date

29 AUG 2013
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics)?

Yes ☒

Consent Date

29 AUG 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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

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

Result	Yes
--------	-----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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

Inclusion Criterion	Subject is aged from 23 to 65 years (inclusive).
---------------------	--

Result	Yes
--------	-----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number	3
----------------------------	---

Inclusion Criterion	Subject is Japanese. <input type="radio"/>
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number

4

Inclusion Criterion

Smoking, healthy subject
as judged
by the Investigator based
on all
available assessments from
the
Screening period/day of
Admission
(e.g. safety laboratory,
spirometry[FEV1/FVC >0.7
at
post-bronchodilator
spirometry,
post-bronchodilator FEV1
>80%
predicted value, and
post-bronchodilator FVC
>80%
predicted value], 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number

5

Inclusion Criterion

Subject smokes at least 10 commercially available menthol mCCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO/mCC, as labelled on the cigarette package, for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last three 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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

Inclusion Criterion	The subject does not plan to quit smoking in the next 3 months.	<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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Inclusion Criteria (7)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number	7
----------------------------	---

Inclusion Criterion	The subject is ready to accept interruptions of smoking for up to 90 days.
---------------------	--

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

Exclusion Criterion Number

3

Exclusion Criterion

The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator.

Result

No

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 32 kg/m ² .
---------------------	--

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

Exclusion Criterion Number

5

Exclusion Criterion

As per Investigator or
designee 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	Concomitant use of NSAIDs <input checked="" type="radio"/> or acetylsalicylic acid.
---------------------	---

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

Exclusion Criterion Number	11
----------------------------	----

Exclusion Criterion	The subject has a positive urine drug test.
---------------------	---

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	Positive serology test for HIV1/2, hepatitis B or hepatitis C.
---------------------	--

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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, child).
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	The subject has previously participated in the same study at a different time (i.e. each subject can be included in the study population only once).
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Demographics

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

Date of Birth	(b) (6)
Sex	Female <input checked="" type="radio"/>
Is the subject Japanese?	Yes <input checked="" type="radio"/>
Date the Subject signed the Main Informed Consent	29 AUG 2013 DD/MMM/YYYY
Time the Subject signed the Main Informed Consent	09:25 hour:min 24-hour clock
Age(Derived)	23

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (Heart1) 29 Oct 2014 03:06:07

Generated On: 17 Jul 2016 22:26:21

Date of collection

29 AUG 2013
DD/MMM/YYYY

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

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (Heart1) 29 Oct 2014 03:06:07

Generated On: 17 Jul 2016 22:26:21

Date of collection

29 AUG 2013
DD/MMM/YYYY

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

No ☒

Number

Diagnosis Description

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

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

29 AUG 2013
DD/MMM/YYYY

Time of assessment

09:59
hour:min 24-hour clock

Pulse rate

63
beats per minute

Respiratory rate

17
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

59
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (1)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (2)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (3)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (4)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (5)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (6)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (7)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (8)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (9)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (10)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (11)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (12)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (13)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (14)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (15)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (16)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (17)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (18)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Physical Examination (19)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Date	29 AUG 2013 DD/MMM/YYYY
------	----------------------------

Brand name	MARLBORO ICE BLAST 5 BOX
------------	--------------------------

ISO Tar Yield	5 MG
---------------	---------

ISO Nicotine Yield	0.4 MG
--------------------	-----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Has the subject seen a THS 2.2 menthol product demonstration?

Yes ☒

If the subject did not see the demonstration please explain

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Smoking History

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Date of Assessment

29 AUG 2013
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next 3 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: FTND Questionnaire

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Type	FAGERSTROM TEST FOR NICOTINE DEPENDENCE
------	--

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

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

Date of assessment	29 AUG 2013
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	09:35
	hour:min 24-hour clock

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

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

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

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

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	No <input type="radio"/>
---	--------------------------

6. Do you smoke even if you are so ill that you are in bed most of the day?	Yes <input type="radio"/>
---	---------------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Weight and Height

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

Weight

49.1
kg

Height

155
cm

BMI (Derived)

20.4
kg/m2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment:

29 AUG 2013
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

61
beats per minute

QRS Interval

82
msec

QT Interval

420
msec

QTcB Interval

424
msec

PR Interval

162
msec

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (Heart1) 29 Oct 2014 03:06:05

Generated On: 17 Jul 2016 22:26:21

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Spirometry (1)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Date of assessment 29 AUG 2013
DD/MMM/YYYY

Time of assessment 10:53

Predicted FVC value 3.26
L

Best measured FVC value 2.85
L

Percent of predicted FVC value 87.4
%

Best measured FEV1 value 2.11
L

Predicted FEV1 value 2.90
L

Percent of predicted FEV1 value 72.7
%

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Spirometry (1)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

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

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

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Spirometry (2)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Date of assessment 29 AUG 2013
DD/MMM/YYYY

Time of assessment 11:14

Name of bronchodilator SULTANOL INHALER

Dose 100UG

Predicted FVC value 3.26
L

Best measured FVC value 2.91
L

Percent of predicted FVC value 89.2
%

Best measured FEV1 value 2.47
L

Predicted FEV1 value 2.90
L

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Spirometry (2)

Data signed: (Heart1) 29 Oct 2014 03:06:08

Generated On: 17 Jul 2016 22:26:21

Percent of predicted FEV1 value	85.1 %
---------------------------------	-----------

Calculated ratio between FEV1/FVC	0.85
-----------------------------------	------

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Chest X-Ray

Data signed: (Heart1) 29 Oct 2014 03:06:09

Generated On: 17 Jul 2016 22:26:21

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Haematology

Data signed: (Heart1) 29 Oct 2014 03:06:07

Generated On: 17 Jul 2016 22:26:21

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 ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Clinical Chemistry

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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 ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Urine analysis

Data signed: (Heart1) 29 Oct 2014 03:06:07

Generated On: 17 Jul 2016 22:26:21

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (Heart1) 29 Oct 2014 03:06:07

Generated On: 17 Jul 2016 22:26:21

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Urine Drug Screen

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Date of sample collection	29 AUG 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	9:42 hour:min 24-hour clock
---------------------------	--------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Alcohol Breath Test

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

29 AUG 2013
DD/MMM/YYYY

Time of assessment

09:53
hour:min 24-hour clock

Result

Negative ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Urine Pregnancy Test

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Category Pregnancy Testing ☒

Not Done False

If Not Done, specify reason _____

Date of Test 29 AUG 2013
DD/MMM/YYYY

Time of Test 09:42
hour:min 24-hour clock

Specify result Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Urine Cotinine Test

Data signed: (Heart1) 29 Oct 2014 03:06:06

Generated On: 17 Jul 2016 22:26:21

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	29 AUG 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	9:42 hour:min 24-hour clock
---------------------------	--------------------------------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU SEROLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	POS/NEG_HC
Result	
Text Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	
Clinically Significant?	
Comment	
Result Category	S

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU SEROLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Text Result Code	066
Reference Value Category	S
Timepoint(COHB)	
Material Code	SERUM
Chyle Comment Code	
Chyle Comment English	
Hemolysis Comment Code	
Hemolysis Comment English	
Specimen Comment Code 1	
Specimen English Comment 1	
Specimen Comment Code 2	
Specimen English Comment 2	
Result Supplementary Comment Code 1	
Result Supplementary English Comment Code 1	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU SEROLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU SEROLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	POS/NEG_HBS
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	
Comment	
Result Category	S

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU SEROLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Text Result Code	168
Reference Value Category	S
Timepoint(COHB)	
Material Code	SERUM
Chyle Comment Code	
Chyle Comment English	
Hemolysis Comment Code	
Hemolysis Comment English	
Specimen Comment Code 1	
Specimen English Comment 1	
Specimen Comment Code 2	
Specimen English Comment 2	
Result Supplementary Comment Code 1	
Result Supplementary English Comment Code 1	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU SEROLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:10

Generated On: 17 Jul 2016 22:26:21

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category

BLOOD CHEMISTRY

Date of Sample Collection

2013 AUG 29

Date (BU)

2013/08/29

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	TOTAL PROTEIN
Result	7.2
Text Result	
Unit	G/DL
Lower limit	6.7
Upper limit	8.3
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	ALBUMIN
Result	4.6
Text Result	
Unit	G/DL
Lower limit	3.8
Upper limit	5.3
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	TOTAL BILIRUBIN
Result	0.9
Text Result	
Unit	MG/DL
Lower limit	0.2
Upper limit	1.2
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	<hr/>
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Comment	<hr/>
---------	-------

Result Category	N
-----------------	---

Text Result Code	<hr/>
------------------	-------

Reference Value Category	-
--------------------------	---

Timepoint(COHB)	<hr/>
-----------------	-------

Material Code	SERUM
---------------	-------

Chyle Comment Code	<hr/>
--------------------	-------

Chyle Comment English	<hr/>
-----------------------	-------

Hemolysis Comment Code	<hr/>
------------------------	-------

Hemolysis Comment English	<hr/>
---------------------------	-------

Specimen Comment Code 1	<hr/>
-------------------------	-------

Specimen English Comment 1	<hr/>
----------------------------	-------

Specimen Comment Code 2	<hr/>
-------------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	DIRECT BILIRUBIN
Result	0.2
Text Result	
Unit	MG/DL
Lower limit	0.0
Upper limit	0.3
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	AST
Result	14
Text Result	
Unit	U/L
Lower limit	10
Upper limit	40
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	<hr/>
-------------------------	-------

Comment	<hr/>
---------	-------

Result Category	N
-----------------	---

Text Result Code	<hr/>
------------------	-------

Reference Value Category	-
--------------------------	---

Timepoint(COHB)	<hr/>
-----------------	-------

Material Code	SERUM
---------------	-------

Chyle Comment Code	<hr/>
--------------------	-------

Chyle Comment English	<hr/>
-----------------------	-------

Hemolysis Comment Code	<hr/>
------------------------	-------

Hemolysis Comment English	<hr/>
---------------------------	-------

Specimen Comment Code 1	<hr/>
-------------------------	-------

Specimen English Comment 1	<hr/>
----------------------------	-------

Specimen Comment Code 2	<hr/>
-------------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	ALT
Result	8
Text Result	
Unit	U/L
Lower limit	5
Upper limit	45
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	LDH
Result	133
Text Result	
Unit	U/L
Lower limit	120
Upper limit	240
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	AP
Result	172
Text Result	
Unit	U/L
Lower limit	100
Upper limit	325
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	_____
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Comment	_____
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Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	SERUM
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Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
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Hemolysis Comment English	_____
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Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	GGT
Result	8
Text Result	
Unit	U/L
Lower limit	
Upper limit	30
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ E

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	FASTING GLUCOSE
Result	80
Text Result	
Unit	MG/DL
Lower limit	70
Upper limit	109
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	CREATININE
Result	0.39
Text Result	
Unit	MG/DL
Lower limit	0.47
Upper limit	0.79
Flag	Low 

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?

No ☒

Comment

Result Category

N

Text Result Code

Reference Value Category

-

Timepoint(COHB)

Material Code

SERUM

Chyle Comment Code

Chyle Comment English

Hemolysis Comment Code

Hemolysis Comment English

Specimen Comment Code 1

Specimen English Comment 1

Specimen Comment Code 2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	BUN
Result	6
Text Result	
Unit	MG/DL
Lower limit	8
Upper limit	23
Flag	Low 

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?

No ☒

Comment

Result Category

N

Text Result Code

Reference Value Category

-

Timepoint(COHB)

Material Code

SERUM

Chyle Comment Code

Chyle Comment English

Hemolysis Comment Code

Hemolysis Comment English

Specimen Comment Code 1

Specimen English Comment 1

Specimen Comment Code 2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	TRIGLYCERIDES
Result	54
Text Result	
Unit	MG/DL
Lower limit	30
Upper limit	149
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	TOTAL CHOLESTEROL
Result	131
Text Result	
Unit	MG/DL
Lower limit	120
Upper limit	219
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	<hr/>
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Comment	<hr/>
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Result Category	N
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Text Result Code	<hr/>
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Reference Value Category	-
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Timepoint(COHB)	<hr/>
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Material Code	SERUM
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Chyle Comment Code	<hr/>
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Chyle Comment English	<hr/>
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Hemolysis Comment Code	<hr/>
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Hemolysis Comment English	<hr/>
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Specimen Comment Code 1	<hr/>
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Specimen English Comment 1	<hr/>
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Specimen Comment Code 2	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

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Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	SODIUM
Result	138
Text Result	
Unit	MEQ/L
Lower limit	137
Upper limit	147
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	POTASSIUM
Result	3.6
Text Result	
Unit	MEQ/L
Lower limit	3.5
Upper limit	5.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	<hr/>
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Comment	<hr/>
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Result Category	N
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Text Result Code	<hr/>
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Reference Value Category	-
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Timepoint(COHB)	<hr/>
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Material Code	SERUM
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Chyle Comment Code	<hr/>
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Chyle Comment English	<hr/>
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Hemolysis Comment Code	<hr/>
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Hemolysis Comment English	<hr/>
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Specimen Comment Code 1	<hr/>
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Specimen English Comment 1	<hr/>
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Specimen Comment Code 2	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:11

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Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
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Date of Sample Collection	2013 AUG 29
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Date (BU)	2013/08/29
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Please document clinically relevant abnormalities in the AE form	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	WBC COUNT
Result	8600
Text Result	
Unit	/UL
Lower limit	3300
Upper limit	9000
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	RBC COUNT
Result	439
Text Result	
Unit	10 ⁴ /UL
Lower limit	380
Upper limit	500
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

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Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	HEMOGLOBIN
Result	12.8
Text Result	
Unit	G/DL
Lower limit	11.5
Upper limit	15.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

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Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

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Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	HEMATOCRIT
Result	38.6
Text Result	
Unit	%
Lower limit	34.8
Upper limit	45.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	MCV
Result	88
Text Result	
Unit	FL
Lower limit	85
Upper limit	102
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	MCH
Result	29.2
Text Result	
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	MCHC
Result	33.2
Text Result	
Unit	%
Lower limit	30.2
Upper limit	35.1
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	PLATELET COUNT
Result	22.7
Text Result	
Unit	10 ⁴ /UL
Lower limit	14.0
Upper limit	34.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	DIFFERENTIAL WBC
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	NEUTROPHILS (REL)
Result	70.0
Text Result	
Unit	%
Lower limit	40.0
Upper limit	75.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	LYMPHOCYTES (REL)
Result	17.0
Text Result	
Unit	%
Lower limit	18.0
Upper limit	49.0
Flag	Low 

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?

No ☒

Comment

Result Category

N

Text Result Code

Reference Value Category

-

Timepoint(COHB)

Material Code

BLOOD

Chyle Comment Code

Chyle Comment English

Hemolysis Comment Code

Hemolysis Comment English

Specimen Comment Code 1

Specimen English Comment 1

Specimen Comment Code 2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	MONOCYTES (REL)
Result	4.0
Text Result	
Unit	%
Lower limit	2.0
Upper limit	10.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	EOSINOPHILS (REL)
Result	8.0
Text Result	
Unit	%
Lower limit	0.0
Upper limit	8.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	BASOPHILS (REL)
Result	1.0
Text Result	
Unit	%
Lower limit	0.0
Upper limit	2.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	NEUTROPHILS (ABS)
Result	6000
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	LYMPHOCYTES (ABS)
Result	1500
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	MONOCYTES (ABS)
Result	340
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	EOSINOPHILS (ABS)
Result	690
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Test Category	HEMATOLOGY
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	BASOPHILS (ABS)
Result	86
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:16

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
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Date of Sample Collection	2013 AUG 29
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Date (BU)	2013/08/29
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Please document clinically relevant abnormalities in the AE form	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	SPECIFIC GRAVITY
Result	1.006
Text Result	
Unit	
Lower limit	1.002
Upper limit	1.030
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ URINE

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	PH
Result	6.0
Text Result	
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ URINE

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	GLUCOSE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	_____
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Comment	_____
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Result Category	S
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Text Result Code	168
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Reference Value Category	S
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Timepoint(COHB)	_____
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Material Code	URINE
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Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
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Hemolysis Comment English	_____
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Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	PROTEIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	_____
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Comment	_____
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Result Category	S
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Text Result Code	168
------------------	-----

Reference Value Category	S
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Timepoint(COHB)	_____
-----------------	-------

Material Code	URINE
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Chyle Comment Code	_____
--------------------	-------

Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

Hemolysis Comment English	_____
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Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	BILIRUBIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	_____
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Comment	_____
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Result Category	S
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Text Result Code	168
------------------	-----

Reference Value Category	S
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Timepoint(COHB)	_____
-----------------	-------

Material Code	URINE
---------------	-------

Chyle Comment Code	_____
--------------------	-------

Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

Hemolysis Comment English	_____
---------------------------	-------

Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
----------------------------	-------

Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	NITRITE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	_____
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Comment	_____
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Result Category	S
-----------------	---

Text Result Code	168
------------------	-----

Reference Value Category	S
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Timepoint(COHB)	_____
-----------------	-------

Material Code	URINE
---------------	-------

Chyle Comment Code	_____
--------------------	-------

Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

Hemolysis Comment English	_____
---------------------------	-------

Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Test Category	URINALYSIS
Date of Sample Collection	2013 AUG 29
Date (BU)	2013/08/29
Blood Sample time(BU)	1037
Urine Sample time(BU)	0942
Time of Blood Sample Collection	10:37
Time of Urine Sample Collection	09:42
Test Name	OCCULT BLOOD
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Clinically Significant?	_____
-------------------------	-------

Comment	_____
---------	-------

Result Category	S
-----------------	---

Text Result Code	168
------------------	-----

Reference Value Category	S
--------------------------	---

Timepoint(COHB)	_____
-----------------	-------

Material Code	URINE
---------------	-------

Chyle Comment Code	_____
--------------------	-------

Chyle Comment English	_____
-----------------------	-------

Hemolysis Comment Code	_____
------------------------	-------

Hemolysis Comment English	_____
---------------------------	-------

Specimen Comment Code 1	_____
-------------------------	-------

Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
-------------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Screening

Form: Lab-BU URINALYSIS(2013 AUG 29)

Data signed: (Heart1) 29 Oct 2014 03:06:24

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004536593

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

Date of Visit

19 SEP 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (Heart1) 29 Oct 2014 03:06:29

Generated On: 17 Jul 2016 22:26:21

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 03:06:29

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number

4

Inclusion Criterion

Smoking, healthy subject
as judged
by the Investigator based
on all
available assessments from
the
Screening period/day of
Admission
(e.g. safety laboratory,
spirometry[FEV1/FVC >0.7
at
post-bronchodilator
spirometry,
post-bronchodilator FEV1
>80%
predicted value, and
post-bronchodilator FVC
>80%
predicted value], 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 03:06:29

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number

5

Inclusion Criterion

Subject smokes at least 10 commercially available menthol mCCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO/mCC, as labelled on the cigarette package, for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last three 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 03:06:29

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number	7
----------------------------	---

Inclusion Criterion	The subject is ready to accept interruptions of smoking for up to 90 days.
---------------------	--

Result	Yes
--------	-----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 03:06:29

Generated On: 17 Jul 2016 22:26:21

Inclusion Criterion Number	8
----------------------------	---

Inclusion Criterion	The subject is ready to accept using the THS 2.2 Menthol.
---------------------	---

Result	Yes
--------	-----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

Exclusion Criterion Number

3

Exclusion Criterion

The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator.

Result

No

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥32 kg/m2.
---------------------	---

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	As per Investigator or designee 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	Concomitant use of NSAIDs <input type="radio"/> or acetylsalicylic acid.
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

Exclusion Criterion Number	11
----------------------------	----

Exclusion Criterion	The subject has a positive urine drug test.
---------------------	---

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

Exclusion Criterion	For women only: Subject does not agree to use an acceptable method of effective contraception <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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

15:07
hour:min 24-hour clock

Pulse rate

69
beats per minute

Respiratory rate

15
breaths per minute

Blood Pressure (systolic)

104
mmHg

Blood Pressure (diastolic)

67
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Product preference

Data signed: (Heart1) 29 Oct 2014 03:06:33

Generated On: 17 Jul 2016 22:26:21

Which product would you prefer to be randomized to:

mCC ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (Heart1) 29 Oct 2014 03:06:33

Generated On: 17 Jul 2016 22:26:21

Has the subject received advices on the risks of
smoking?

Yes ☐

Has a debriefing been performed about THS 2.2?

Yes ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (Heart1) 29 Oct 2014 03:06:33

Generated On: 17 Jul 2016 22:26:21

Brand name	MARLBORO ICE BLAST 5 BOX
------------	--------------------------

ISO Tar Yield	5 MG
---------------	---------

ISO Nicotine Yield	0.4 MG
--------------------	-----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (Heart1) 29 Oct 2014 03:06:33

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (Heart1) 29 Oct 2014 03:06:33

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Weight

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

19 SEP 2013
DD/MMM/YYYY

Time of assessment

14:58
hour:min 24-hour clock

Weight

48.8
kg

Waist circumference

74
cm

BMI

20.3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Time of sample collection	14:35
	hour:min 24-hour clock

Drug type	Result
-----------	--------

Amphetamines	Negative
--------------	----------

Barbiturates	Negative
--------------	----------

Benzodiazepines	Negative
-----------------	----------

Cannabinoids	Negative
--------------	----------

Cocaine	Negative
---------	----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

Drug type	Result
Opiates	Negative

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Alcohol Breath Test

Data signed: (Heart1) 29 Oct 2014 03:06:29

Generated On: 17 Jul 2016 22:26:21

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

14:53
hour:min 24-hour clock

Result

Negative ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Urine Pregnancy Test

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, specify reason

Time of Test

14:35
hour:min 24-hour clock

Specify result

Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: Urine Cotinine Test

Data signed: (Heart1) 29 Oct 2014 03:06:30

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Time of Sample Collection	14:35
	hour:min 24-hour clock

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (Heart1) 29 Oct 2014 03:06:28

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	14:54
	hour:min 24-hour clock

Result	6
	ppm

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Date of Visit

20 SEP 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:15
hour:min 24-hour clock

Pulse rate

65
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

60
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

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	06:38
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

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	12:05
---	-------

Result(ppm)	4
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

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	16:25
---	-------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (Heart1) 29 Oct 2014 03:06:34

Generated On: 17 Jul 2016 22:26:21

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	20:06
---	-------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Start Time	06:30
	hour:min 24-hour clock

End Date	21 SEP 2013
	DD/MMM/YYYY

End Time	06:29
	hour:min 24-hour clock

Volume	1611
--------	------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Type	QUESTIONNAIRE ON SMOKING URGES
Was paper questionnaire used?	No <input checked="" type="radio"/>
Reason not done	THE SC FORGOT TO GIVE THE PAPER FORM TO THE SUBJECT.
Date of assessment	
DD/MMM/YYYY	
Time of assessment	
hour:min 24-hour clock	
1. I have a desire for a cigarette right now	
2. Nothing would be better than smoking a cigarette right now	
3. If it were possible I would probably smoke now	
4. I could control things better right now if I could smoke	
5. All I want right now is a cigarette	
6. I have an urge for a cigarette	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

7. A cigarette would taste good now

8. I would do almost anything for a cigarette now

9. Smoking would make me less depressed

10. I am going to smoke as soon as possible

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Was smoking satisfying? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did cigarettes taste good? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy the ☒
sensation in your throat
and chest?

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking calm you
down? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒
more awake?

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒
less irritable?

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking help you
concentrate? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking reduce your ☒
hunger for food?

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you
dizzy? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you
nauseous? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking immediately ☒
relieve your craving for a
cigarette?

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (Heart1) 29 Oct 2014 03:06:35

Generated On: 17 Jul 2016 22:26:21

Was paper questionnaire used?

No ☒

Reason not done

THE SC FORGOT TO GIVE THE
PAPER FORM TO THE
SUBJECT.

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy smoking? ☒

Response

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type

URINE

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000171
Analyte	3-HPMA
Result	422
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000171
Analyte	CEMA
Result	55.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000171
Analyte	HBMA
Result	165
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001231
Analyte	NNAL
Result	72.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001231
Analyte	NNN
Result	7.13
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112210000611
Analyte	HEMA
Result	4.50
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-05
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000171
Analyte	COT
Result	793
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000171
Analyte	NIC
Result	780
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000171
Analyte	NIC-GLUC
Result	690
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000171
Analyte	THCOT
Result	577
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000171
Analyte	COT-GLUC
Result	2210
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000171
Analyte	THCOT-GLUC
Result	104
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112230000611
Analyte	3-OH BAP
Result	59.7
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-07
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000611
Analyte	1-NA
Result	50.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000611
Analyte	2-NA
Result	12.6
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000611
Analyte	4-ABP
Result	6.85
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000611
Analyte	O-TOL
Result	83.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113640000611
Analyte	1-OHP
Result	72.6
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-03
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000611
Analyte	SBMA
Result	0.997
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000611
Analyte	SPMA
Result	2.10
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113630000611
Analyte	MHBMA
Result	0.758
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-02
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113730000428
Analyte	CREATININE
Result	40.0
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-14
Date of Collection	2013-SEP-20
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:29

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2013 SEP 20)

Data signed: (Heart1) 29 Oct 2014 03:06:36

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
---------------	-----------

Date of Sample Collection	2013 SEP 20
---------------------------	-------------

Date (BU)	2013/09/20
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Please document clinically relevant abnormalities in the AE form	
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2013 SEP 20)

Data signed: (Heart1) 29 Oct 2014 03:06:36

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
Date of Sample Collection	2013 SEP 20
Date (BU)	2013/09/20
Blood Sample time(BU)	2012
Urine Sample time(BU)	
Time of Blood Sample Collection	20:12
Time of Urine Sample Collection	
Test Name	COHB
Result	4.7
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2013 SEP 20)

Data signed: (Heart1) 29 Oct 2014 03:06:36

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2013 SEP 20)

Data signed: (Heart1) 29 Oct 2014 03:06:36

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004537935

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

Date of Visit

21 SEP 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (Heart1) 29 Oct 2014 03:06:39

Generated On: 17 Jul 2016 22:26:21

Randomization number (4 digits)	3023
---------------------------------	------

Allocation Arm	SA <input checked="" type="radio"/>
----------------	-------------------------------------

Cigarette Consumption	10 – 19 conventional menthol cigarettesper day <input checked="" type="radio"/>
-----------------------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

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

10:47
hour:min 24-hour clock

Pulse rate

67
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

62
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 03:06:42

Generated On: 17 Jul 2016 22:26:21

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Time of assessment 6:46
hour:min 24-hour clock

Predicted FVC value 3.26
L

Best measured FVC value 2.79
L

Percent of predicted FVC value 85.5
%

Best measured FEV1 value 2.16
L

Predicted FEV1 value 2.90
L

Percent of predicted FEV1 value 74.4
%

Interpretation Abnormal ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 03:06:42

Generated On: 17 Jul 2016 22:26:21

If Abnormal, Clinical Significance

Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please PREDICTED FEV1 VALUE
specify the finding(s) 74.4%

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (Heart1) 29 Oct 2014 03:06:40

Generated On: 17 Jul 2016 22:26:21

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 ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (Heart1) 29 Oct 2014 03:06:40

Generated On: 17 Jul 2016 22:26:21

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 ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (Heart1) 29 Oct 2014 03:06:40

Generated On: 17 Jul 2016 22:26:21

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (Heart1) 29 Oct 2014 03:06:42

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record Number

21 SEP 2013

20:16

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (Heart1) 29 Oct 2014 03:06:40

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record number

21 SEP 2013

20:16

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 03:06:40

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (Heart1) 29 Oct 2014 03:06:39

Generated On: 17 Jul 2016 22:26:21

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	06:53
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (Heart1) 29 Oct 2014 03:06:39

Generated On: 17 Jul 2016 22:26:21

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	12:10
---	-------

Result(ppm)	15
-------------	----

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (Heart1) 29 Oct 2014 03:06:39

Generated On: 17 Jul 2016 22:26:21

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	16:06
---	-------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (Heart1) 29 Oct 2014 03:06:39

Generated On: 17 Jul 2016 22:26:21

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	20:04
---	-------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (Heart1) 29 Oct 2014 03:06:41

Generated On: 17 Jul 2016 22:26:21

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

21 SEP 2013

6:48

trans-3'-hydroxyc
otinine

21 SEP 2013

6:48

cotinine

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (Heart1) 29 Oct 2014 03:06:41

Generated On: 17 Jul 2016 22:26:21

Time of caffeine tablet intake	10:08
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
21 SEP 2013	16:08	Caffeine
21 SEP 2013	16:08	Paraxanthine

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064
Folder: Baseline (Day 0)
Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL
Data signed: (Heart1) 29 Oct 2014 03:06:42
Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

21 SEP 2013

06:48

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Risk Marker: s-ICAM-1

Data signed: (Heart1) 29 Oct 2014 03:06:42

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

21 SEP 2013

06:48

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Risk Marker: HbA1c

Data signed: (Heart1) 29 Oct 2014 03:06:42

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

21 SEP 2013

06:48

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

Start Time	06:30
	hour:min 24-hour clock

End Date	22 SEP 2013
	DD/MMM/YYYY

End Time	06:29
	hour:min 24-hour clock

Volume	2026
--------	------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

Were samples 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Generated On: 17 Jul 2016 22:26:21

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

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

Date of assessment	2013 SEP 21
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

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

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

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

3. If it were possible I would probably smoke now	Strongly disagree <input type="radio"/>
---	---

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

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

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

7. A cigarette would taste good now	Strongly disagree <input type="radio"/>
-------------------------------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Generated On: 17 Jul 2016 22:26:21

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly disagree ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2013 SEP 21
DD/MMM/YYYY

Time of assessment

06:04
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

None ☒

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☒

5. Difficulty concentrating

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

How have you been feeling over the past 24 hours?

Slight ☒

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours?

Moderate ☒

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours?

Moderate ☒

8. Restless

How have you been feeling over the past 24 hours?

None ☒

9. Impatient

How have you been feeling over the past 24 hours?

None ☒

10. Constipation

How have you been feeling over the past 24 hours?

None ☒

11. Dizziness

How have you been feeling over the past 24 hours?

None ☒

12. Coughing

How have you been feeling over the past 24 hours?

None ☒

13. Dreaming or nightmares

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 17 Jul 2016 22:26:21

Date of Birth	(b) (6)
Date of assessment= DD/MMM/YYYY	2013 SEP 21 DD/MMM/YYYY
Time of assessment	20:07 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	Little <input type="radio"/>
2. Did cigarettes taste good?	Very little <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Not at all <input type="radio"/>
4. Did smoking calm you down?	Not at all <input type="radio"/>
5. Did smoking make you feel more awake?	Not at all <input type="radio"/>
6. Did smoking make you feel less irritable?	Not at all <input type="radio"/>
7. Did smoking help you concentrate?	Not at all <input type="radio"/>
8. Did smoking reduce your hunger for food?	Not at all <input type="radio"/>
9. Did smoking make you dizzy?	Not at all <input type="radio"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 17 Jul 2016 22:26:21

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Not at all ☐

12. Did you enjoy smoking? Not at all ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Cough Assessment

Generated On: 17 Jul 2016 22:26:21

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2013 SEP 21 DD/MMM/YYYY
Time of assessment	06:02 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="radio"/>
If YES, please answer the following questions:	
First Question: Cough Impact Scale How much is your cough bothering you?	14
Second Question: Cough Intensity Scale: How intense is your cough?	Very mild <input type="radio"/>
Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Sometimes <input type="radio"/>
Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	A moderate amount of sputum <input type="radio"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
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Reason not done	
-----------------	--

Date of assessment	21 SEP 2013 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:00 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Strongly agree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :	IT TAKES TIME TO PUT TUBES AND FILTER ON THE DEVICE.
---	---

2. You enjoy smoking with the device as much as without it.	Strongly disagree <input checked="" type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	IT TAKES TIME TO PUT TUBES AND FILTER ON THE DEVICE.
---	---

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input checked="" type="radio"/>
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Agree ☒

If you agree or strongly agree, please describe :

I GUESS SMOKING NUMBER
WILL DECREASE IF I USUALLY
USE THE DEVICE SINCE IT
TAKES TIME.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (Heart1) 29 Oct 2014 03:06:44

Generated On: 17 Jul 2016 22:26:21

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:48
hour:min 24-hour clock

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

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (Heart1) 29 Oct 2014 03:06:43

Generated On: 17 Jul 2016 22:26:21

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Date of Sample Collection

21 SEP 2013
DD/MMM/YYYY

Time of Sample Collection

06:48
hour:min 24-hour clock

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

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type

PLASMA

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112180000131
Analyte	COT
Result	220
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-02
Date of Collection	2013-SEP-21
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112180000131
Analyte	NIC
Result	21.3
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-02
Date of Collection	2013-SEP-21
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (3)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112260000190
Analyte	COT
Result	BLQ<(1.00)
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-10
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (3)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (4)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112260000190
Analyte	THCOT
Result	BLQ<(1.00)
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-10
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (4)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (5)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112240000310
Analyte	CAFFEINE
Result	3270
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99127-08
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (5)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (6)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112240000310
Analyte	PARAXANTHINE
Result	1790
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99127-08
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (6)

Data signed: (Heart1) 29 Oct 2014 03:07:19

Generated On: 17 Jul 2016 22:26:21

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type

URINE

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000172
Analyte	3-HPMA
Result	414
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000172
Analyte	CEMA
Result	54.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000172
Analyte	HBMA
Result	135
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001232
Analyte	NNAL
Result	67.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001232
Analyte	NNN
Result	8.93
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112210000612
Analyte	HEMA
Result	3.75
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-05
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000172
Analyte	COT
Result	713
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000172
Analyte	NIC
Result	630
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000172
Analyte	NIC-GLUC
Result	662
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000172
Analyte	THCOT
Result	445
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000172
Analyte	COT-GLUC
Result	1520
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000172
Analyte	THCOT-GLUC
Result	82.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112230000612
Analyte	3-OH BAP
Result	56.4
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-07
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000612
Analyte	1-NA
Result	54.6
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000612
Analyte	2-NA
Result	12.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000612
Analyte	4-ABP
Result	6.97
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000612
Analyte	O-TOL
Result	81.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112270000286
Analyte	11-DTXB2
Result	305
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-11
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112280000286
Analyte	IPF2A-III
Result	71.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-12
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (45)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113640000612
Analyte	1-OHP
Result	102
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-03
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (45)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (46)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000612
Analyte	SBMA
Result	0.929
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (46)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (47)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000612
Analyte	SPMA
Result	1.83
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (47)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (48)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113630000612
Analyte	MHBMA
Result	0.593
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-02
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (48)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (49)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113310000343
Analyte	AMES
Result	14.3
Result Unit	REV/ML
Lab Status	OK
Sample comment	
Detection method	COUNT
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-15
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (49)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (50)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113730000429
Analyte	CREATININE
Result	40.5
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-14
Date of Collection	2013-SEP-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (50)

Data signed: (Heart1) 04 Nov 2014 07:29:31

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2013 SEP 21)

Data signed: (Heart1) 29 Oct 2014 03:06:44

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
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Date of Sample Collection	2013 SEP 21
---------------------------	-------------

Date (BU)	2013/09/21
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Please document clinically relevant abnormalities in the AE form	
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2013 SEP 21)

Data signed: (Heart1) 29 Oct 2014 03:06:44

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
Date of Sample Collection	2013 SEP 21
Date (BU)	2013/09/21
Blood Sample time(BU)	2016
Urine Sample time(BU)	
Time of Blood Sample Collection	20:16
Time of Urine Sample Collection	
Test Name	COHB
Result	4.6
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2013 SEP 21)

Data signed: (Heart1) 29 Oct 2014 03:06:44

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2013 SEP 21)

Data signed: (Heart1) 29 Oct 2014 03:06:44

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004538015

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1821
------------	--------

Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT10
-------------	-------

Lab Test Name	MONOCYTES
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	0.30
Reported Numeric Result	0.30
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT100

Lab Test Name MCH


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	31
Reported Numeric Result	31
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

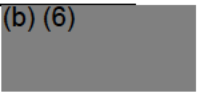
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT102

Lab Test Name MCHC

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	35
Reported Numeric Result	35
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT11

Lab Test Name EOSINOPHILS


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

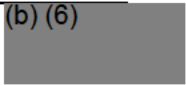
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT12

Lab Test Name BASOPHILS


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	0.08
Reported Numeric Result	0.08
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)


Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT13

Lab Test Name PLATELETS

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	294
Reported Numeric Result	294
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

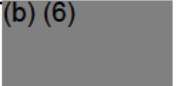
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT2

Lab Test Name HEMATOCRIT


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	41
Reported Numeric Result	41
Reference Range low	34
Reference Range high	48
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT3

Lab Test Name RBC


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	4.7
Reported Numeric Result	4.7
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT4

Lab Test Name MCV

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	88
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Reported Numeric Result	88
-------------------------	----

Reference Range low	79
---------------------	----

Reference Range high	98
----------------------	----

Range Units	FL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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SI Numeric Result	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT40

Lab Test Name HEMOGLOBIN

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14.3
Reported Numeric Result	14.3
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

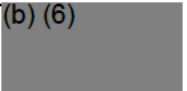
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT7

Lab Test Name WBC

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.01
Reported Numeric Result	7.01
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)


Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT71

Lab Test Name RBC MORPHOLOGY 1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)


Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

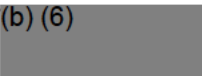
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT8

Lab Test Name NEUTROPHILS


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	4.16
Reported Numeric Result	4.16
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT9

Lab Test Name LYMPHOCYTES

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.21
Reported Numeric Result	2.21
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

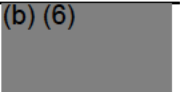
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

Lab Test Name TOTAL BILIRUBIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done <input type="radio"/>
Reported Text Result	0.6
Reported Numeric Result	0.6
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

Lab Test Name TOTAL PROTEIN

Test ID

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done <input type="radio"/>
Reported Text Result	7.3
Reported Numeric Result	7.3
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

Lab Test Name ALBUMIN

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

Lab Test Name ALKALINE PHOSPHATASE

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	54
Reported Numeric Result	54
Reference Range low	31
Reference Range high	106
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

Lab Test Name LDH

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	132
Reported Numeric Result	132
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

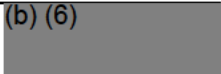
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

Lab Test Name SERUM SODIUM

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done <input type="radio"/>
Reported Text Result	140
Reported Numeric Result	140
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

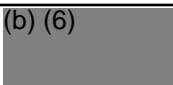
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

Lab Test Name SERUM POTASSIUM

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	3.7
Reported Numeric Result	3.7
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

Lab Test Name DIRECT BILIRUBIN

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

Lab Test Name GGT

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	9
Reported Numeric Result	9
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

Lab Test Name CREATININE (RATE BLANKED)

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	0.6
Reported Numeric Result	0.6
Reference Range low	0.4
Reference Range high	1.1
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)


Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

Lab Test Name ALT (SGPT)

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

Lab Test Name AST (SGOT)

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done <input type="radio"/>
Reported Text Result	15
Reported Numeric Result	15
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

Lab Test Name UREA NITROGEN

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	9
Reported Numeric Result	9
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

Lab Test Name UR NITRITE

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

Lab Test Name UR SPECIFIC GRAVITY

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status

Done 

Reported Text Result

1.014

Reported Numeric Result

1.014

Reference Range low

1.003

Reference Range high

1.035

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

Lab Test Name UR PH

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done <input type="radio"/>
Reported Text Result	6.0
Reported Numeric Result	6.0
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

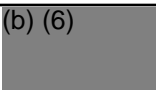
Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

Lab Test Name UR BLOOD

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

(b) (6)

Subject Date of Birth

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

Lab Test Name UR PROTEIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

Lab Test Name UR GLUCOSE

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

Lab Test Name UR BILIRUBIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)


Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

Lab Test Name TRIGLYCERIDES (GPO)

Test ID


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	58
Reported Numeric Result	58
Reference Range low	36
Reference Range high	144
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

Lab Test Name FASTING GLUCOSE

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test Status	Done 
Reported Text Result	79
Reported Numeric Result	79
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B247823

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

Lab Test Name CHOLESTEROL (HIGH
PERFORMANCE)


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	148
Reported Numeric Result	148
Reference Range low	128
Reference Range high	218
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 03:06:45

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:11

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
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Battery Name	FIBRINOGEN
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:11

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
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Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
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Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:11

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	FIBRINOGEN
Test Status	Done <input type="radio"/>
Reported Text Result	289
Reported Numeric Result	289
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	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:11

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:12

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Battery Name	HOMOCYSTEINE
--------------	--------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:12

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:12

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.82
Reported Numeric Result	6.82
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	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:12

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:13

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Battery Name	SICAM-1
--------------	---------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:13

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:13

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	SICAM-1-RUO
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	197.6
Reported Numeric Result	197.6
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	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:13

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Battery Name	HBA1C
--------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1072
------------	--------

Battery Name	HBA1C
--------------	-------

Lab Test ID	HMT370
-------------	--------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	HEMOGLOBIN A1C,VARIANT(-70)
Test Status	Done <input type="radio"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
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	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Battery Name	HDL
--------------	-----

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
Reference Range low	33
Reference Range high	79
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:14

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:15

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Battery Name	LDL
--------------	-----

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:15

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:15

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	59
Reported Numeric Result	59
Reference Range low	60
Reference Range high	148
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:15

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:16

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Battery Name	CRP
--------------	-----

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (2)

Data signed: (Heart1) 29 Oct 2014 03:07:16

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 21
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B247823
--------------	---------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC1088
------------	--------

Battery Name	CRP
--------------	-----

Lab Test ID	SCT1528
-------------	---------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (2)

Data signed: (Heart1) 29 Oct 2014 03:07:16

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test Status	Done <input type="radio"/>
Reported Text Result	<0.020
Reported Numeric Result	
Reference Range low	
Reference Range high	<=0.287
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (2)

Data signed: (Heart1) 29 Oct 2014 03:07:16

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

Date of Visit

22 SEP 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

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

10:34
hour:min 24-hour clock

Pulse rate

63
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

99
mmHg

Blood Pressure (diastolic)

60
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record Number

22 SEP 2013

20:12

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record number

22 SEP 2013

20:10

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: CO Breath Test <SA arm/> (1)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	08:06
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: CO Breath Test <SA arm/> (2)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

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	12:02
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: CO Breath Test <SA arm/> (3)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

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	16:02
---	-------

Result(ppm)	4
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: CO Breath Test <SA arm/> (4)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

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	20:01
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

Start Time	06:30
	hour:min 24-hour clock

End Date	23 SEP 2013
	DD/MMM/YYYY

End Time	06:29
	hour:min 24-hour clock

Volume	1237
--------	------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 03:07:20

Generated On: 17 Jul 2016 22:26:21

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Generated On: 17 Jul 2016 22:26:21

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

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

Date of assessment	2013 SEP 22
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:03
--------------------	-------

hour:min 24-hour clock

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

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

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

3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
---	--------------------------------------

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

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

6. I have an urge for a cigarette	Do not agree or disagree <input type="radio"/>
-----------------------------------	--

7. A cigarette would taste good now	Do not agree or disagree <input type="radio"/>
-------------------------------------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Generated On: 17 Jul 2016 22:26:21

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

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Strongly disagree ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2013 SEP 22
DD/MMM/YYYY

Time of assessment

06:19
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

None ☐

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

How have you been feeling over the past 24 hours?

Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours?

Moderate ☐

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?

Slight ☐

10. Constipation

How have you been feeling over the past 24 hours?

None ☐

11. Dizziness

How have you been feeling over the past 24 hours?

Slight ☐

12. Coughing

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Cough Assessment

Generated On: 17 Jul 2016 22:26:21

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2013 SEP 22
DD/MMM/YYYY

Time of assessment

06:15
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?

13

Second Question: Cough Intensity Scale:
How intense is your cough?

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Blood)

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Sample type

PLASMA

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112180000132
Analyte	COT
Result	154
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99127-02
Date of Collection	2013-SEP-22
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112180000132
Analyte	NIC
Result	0.815
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99127-02
Date of Collection	2013-SEP-22
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type

URINE

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000173
Analyte	3-HPMA
Result	158
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000173
Analyte	CEMA
Result	20.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000173
Analyte	HBMA
Result	86.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001233
Analyte	NNAL
Result	58.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001233
Analyte	NNN
Result	1.47
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112210000613
Analyte	HEMA
Result	3.16
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-05
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000173
Analyte	COT
Result	862
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000173
Analyte	NIC
Result	85.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000173
Analyte	NIC-GLUC
Result	294
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000173
Analyte	THCOT
Result	765
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000173
Analyte	COT-GLUC
Result	2660
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000173
Analyte	THCOT-GLUC
Result	118
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112230000613
Analyte	3-OH BAP
Result	34.7
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-07
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000613
Analyte	1-NA
Result	13.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000613
Analyte	2-NA
Result	4.85
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000613
Analyte	4-ABP
Result	4.49
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000613
Analyte	O-TOL
Result	57.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113640000613
Analyte	1-OHP
Result	95.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99599-03
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000613
Analyte	SBMA
Result	1.48
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000613
Analyte	SPMA
Result	1.20
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113630000613
Analyte	MHBMA
Result	0.196
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99599-02
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113730000430
Analyte	CREATININE
Result	53.8
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99127-14
Date of Collection	2013-SEP-22
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:32

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Lab-BU BIOMARKER(2013 SEP 22)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
---------------	-----------

Date of Sample Collection	2013 SEP 22
---------------------------	-------------

Date (BU)	2013/09/22
-----------	------------

Please document clinically relevant abnormalities in the AE form	
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Lab-BU BIOMARKER(2013 SEP 22)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
Date of Sample Collection	2013 SEP 22
Date (BU)	2013/09/22
Blood Sample time(BU)	2012
Urine Sample time(BU)	
Time of Blood Sample Collection	20:12
Time of Urine Sample Collection	
Test Name	COHB
Result	2.1
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Lab-BU BIOMARKER(2013 SEP 22)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 1

Form: Lab-BU BIOMARKER(2013 SEP 22)

Data signed: (Heart1) 29 Oct 2014 03:07:21

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004538085

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

Date of Visit

23 SEP 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

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

10:40
hour:min 24-hour clock

Pulse rate

60
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

104
mmHg

Blood Pressure (diastolic)

53
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record Number

23 SEP 2013

20:09

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record number

23 SEP 2013

20:09

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: CO Breath Test <SA arm/> (1)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	9:16
---	------

Result(ppm)	1
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: CO Breath Test <SA arm/> (2)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:01
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: CO Breath Test <SA arm/> (3)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

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	16:02
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: CO Breath Test <SA arm/> (4)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:00
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

Start Time	6:30
	hour:min 24-hour clock

End Date	24 SEP 2013
	DD/MMM/YYYY

End Time	6:29
	hour:min 24-hour clock

Volume	2024
--------	------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 03:07:24

Generated On: 17 Jul 2016 22:26:21

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Generated On: 17 Jul 2016 22:26:21

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

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

Date of assessment	2013 SEP 23
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:02
--------------------	-------

hour:min 24-hour clock

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

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

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

3. If it were possible I would probably smoke now	Agree <input type="radio"/>
---	-----------------------------

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

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

6. I have an urge for a cigarette	Do not agree or disagree <input type="radio"/>
-----------------------------------	--

7. A cigarette would taste good now	Agree <input type="radio"/>
-------------------------------------	-----------------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Generated On: 17 Jul 2016 22:26:21

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly disagree ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2013 SEP 23
DD/MMM/YYYY

Time of assessment

06:04
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

How have you been feeling over the past 24 hours?

Moderate ☒

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours?

Severe ☒

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?

Moderate ☒

10. Constipation

How have you been feeling over the past 24 hours?

None ☒

11. Dizziness

How have you been feeling over the past 24 hours?

Slight ☒

12. Coughing

How have you been feeling over the past 24 hours?

None ☒

13. Dreaming or nightmares

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Cough Assessment

Generated On: 17 Jul 2016 22:26:21

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2013 SEP 23 DD/MMM/YYYY
Time of assessment	06:01 hour:min 24-hour clock
Assessment Status	Completed <input checked="" type="radio"/>
Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input checked="" type="radio"/>
If YES, please answer the following questions:	
First Question: Cough Impact Scale How much is your cough bothering you?	8
Second Question: Cough Intensity Scale: How intense is your cough?	Mild <input checked="" type="radio"/>
Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Sometimes <input checked="" type="radio"/>
Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	No sputum <input checked="" type="radio"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Blood)

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Sample type

PLASMA

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112180000133
Analyte	COT
Result	72.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99127-02
Date of Collection	2013-SEP-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112180000133
Analyte	NIC
Result	0.206
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99127-02
Date of Collection	2013-SEP-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Urine End Day

2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type

URINE

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000174
Analyte	3-HPMA
Result	122
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000174
Analyte	CEMA
Result	6.46
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112190000174
Analyte	HBMA
Result	91.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-03
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001234
Analyte	NNAL
Result	31.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112200001234
Analyte	NNN
Result	BLQ<(0.200)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-04
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112210000614
Analyte	HEMA
Result	1.14
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-05
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000174
Analyte	COT
Result	394
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000174
Analyte	NIC
Result	15.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000174
Analyte	NIC-GLUC
Result	20.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000174
Analyte	THCOT
Result	319
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000174
Analyte	COT-GLUC
Result	1140
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112290000174
Analyte	THCOT-GLUC
Result	53.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-13
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112230000614
Analyte	3-OH BAP
Result	BLQ<(25.0)
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-07
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000614
Analyte	1-NA
Result	5.23
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000614
Analyte	2-NA
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000614
Analyte	4-ABP
Result	1.54
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05112250000614
Analyte	O-TOL
Result	59.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-09
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113640000614
Analyte	1-OHP
Result	57.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99599-03
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000614
Analyte	SBMA
Result	1.41
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113620000614
Analyte	SPMA
Result	0.378
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99599-01
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113630000614
Analyte	MHBMA
Result	0.128
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99599-02
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Sample type	URINE
Sample Barcode	05113730000431
Analyte	CREATININE
Result	39.7
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99127-14
Date of Collection	2013-SEP-23
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 07:29:33

Generated On: 17 Jul 2016 22:26:21

Urine End Day

3

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Lab-BU BIOMARKER(2013 SEP 23)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
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Date of Sample Collection	2013 SEP 23
---------------------------	-------------

Date (BU)	2013/09/23
-----------	------------

Please document clinically relevant abnormalities in the AE form	
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Lab-BU BIOMARKER(2013 SEP 23)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

Test Category	BIOMARKER
Date of Sample Collection	2013 SEP 23
Date (BU)	2013/09/23
Blood Sample time(BU)	2009
Urine Sample time(BU)	
Time of Blood Sample Collection	20:09
Time of Urine Sample Collection	
Test Name	COHB
Result	2.0
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Lab-BU BIOMARKER(2013 SEP 23)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 2

Form: Lab-BU BIOMARKER(2013 SEP 23)

Data signed: (Heart1) 29 Oct 2014 03:07:25

Generated On: 17 Jul 2016 22:26:21

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004538181

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Date of Visit

24 SEP 2013
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

DISCONTINUE AFTER
RANDOMIZATION

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Not Done

True

If Not Done, please specify the reason:

DISCONTINUE AFTER RANDOMIZATION.

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Not Done

True

If Not Done, please specify the reason:

DISCONTINUE AFTER RANDOMIZATION.

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Not Done

True

If Not Done, please specify the reason:

DISCONTINUE AFTER
RANDOMIZATION.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: CO Breath Test <SA arm/> (1)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	08:02
---	-------

Result(ppm)	0
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: CO Breath Test <SA arm/> (2)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	DISCONTINUE AFTER RANDOMIZATION.
---	-------------------------------------

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: CO Breath Test <SA arm/> (3)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	DISCONTINUE AFTER RANDOMIZATION.
---	-------------------------------------

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: CO Breath Test <SA arm/> (4)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	DISCONTINUE AFTER RANDOMIZATION.
---	-------------------------------------

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Start Time

End Date

End Time

Volume

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 03:07:27

Generated On: 17 Jul 2016 22:26:21

Were samples collected? _____

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2013 SEP 24
DD/MMM/YYYY

Time of assessment

06:03
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

None ☒

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☒

5. Difficulty concentrating

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

How have you been feeling over the past 24 hours?

Slight ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours?

Severe ☐

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?

Moderate ☐

10. Constipation

How have you been feeling over the past 24 hours?

None ☐

11. Dizziness

How have you been feeling over the past 24 hours?

None ☐

12. Coughing

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Cough Assessment

Generated On: 17 Jul 2016 22:26:21

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2013 SEP 24
DD/MMM/YYYY

Time of assessment

06:00
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	DISCONTINUE AFTER RANDOMIZATION
-----------------	------------------------------------

Date of assessment

DD/MMM/YYYY

Time of assessment

hour:min 24-hour clock

1. I have a desire for a cigarette right now

2. Nothing would be better than smoking a cigarette
right now

3. If it were possible I would probably smoke now

4. I could control things better right now if I could smoke

5. All I want right now is a cigarette

6. I have an urge for a cigarette

7. A cigarette would taste good now

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Day 3

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

8. I would do almost anything for a cigarette now

9. Smoking would make me less depressed

10. I am going to smoke as soon as possible

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

Date of Visit

24 SEP 2013
DD/MMM/YYYY

Discharge Time

12:00
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

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

10:04
hour:min 24-hour clock

Pulse rate

73
beats per minute

Respiratory rate

19
breaths per minute

Blood Pressure (systolic)

116
mmHg

Blood Pressure (diastolic)

59
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Weight

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

24 SEP 2013
DD/MMM/YYYY

Time of assessment

10:35
hour:min 24-hour clock

Weight

50.0
kg

BMI

20.8

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 66
beats per minute

QRS Interval 82
msec

QT Interval 410
msec

QTcB Interval 430
msec

PR Interval 166
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Time of assessment 10:45
hour:min 24-hour clock

Predicted FVC value 3.26
L

Best measured FVC value 2.87
L

Percent of predicted FVC value 88.0
%

Best measured FEV1 value 2.11
L

Predicted FEV1 value 2.90
L

Percent of predicted FEV1 value 72.7
%

Interpretation Abnormal ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

If Abnormal, Clinical Significance

Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please PREDICTED FEV1 VALUE
specify the finding(s) 72.7%

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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 ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

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 ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (Heart1) 29 Oct 2014 03:07:29

Generated On: 17 Jul 2016 22:26:21

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Urine Pregnancy Test

Data signed: (Heart1) 29 Oct 2014 03:07:30

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, specify reason

Time of Test	10:43
	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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (Heart1) 29 Oct 2014 03:07:28

Generated On: 17 Jul 2016 22:26:21

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	10:45
	hour:min 24-hour clock

Result	1
	ppm

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Biomarker(Blood)

Data signed: (Heart1) 04 Nov 2014 07:29:34

Generated On: 17 Jul 2016 22:26:21

Sample type

PLASMA

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 04 Nov 2014 07:29:34

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112260000191
Analyte	COT
Result	47.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	
Celerion Study Number	AA99127-10
Date of Collection	2013-SEP-24
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 04 Nov 2014 07:29:34

Generated On: 17 Jul 2016 22:26:21

Urine End Day

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 04 Nov 2014 07:29:34

Generated On: 17 Jul 2016 22:26:21

Sample type	PLASMA
Sample Barcode	05112260000191
Analyte	THCOT
Result	6.23
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	
Celerion Study Number	AA99127-10
Date of Collection	2013-SEP-24
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 04 Nov 2014 07:29:34

Generated On: 17 Jul 2016 22:26:21

Urine End Day

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date

2013 09 24

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
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Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.33
Reported Numeric Result	0.33
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
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Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	29
Reported Numeric Result	29
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
------------	--------

Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.18
Reported Numeric Result	0.18
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
----------------------	--

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B264214
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Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.06
Reported Numeric Result	0.06
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B264214
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Actual Collection Time	10:43
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Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	279
Reported Numeric Result	279
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" 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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B264214
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Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	4.1
Reference Range high	5.6
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.0
Reported Numeric Result	13.0
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1821
------------	--------

Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT7
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.51
Reported Numeric Result	8.51
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1821
------------	--------

Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
--------------	----------------------------------

Lab Test ID	HMT71
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	RBC MORPHOLOGY 1
Test ID	
Test Status	Done <input type="radio"/>
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT8
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.43
Reported Numeric Result	6.43
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1821
------------	--------

Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
--------------	----------------------------------

Lab Test ID	HMT9
-------------	------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.49
Reported Numeric Result	1.49
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

Lab Test Name	TOTAL BILIRUBIN
---------------	-----------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT12
-------------	-------

Lab Test Name	TOTAL PROTEIN
---------------	---------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.5
Reported Numeric Result	7.5
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT13
-------------	-------

Lab Test Name	ALBUMIN
---------------	---------


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	4.5
Reported Numeric Result	4.5
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1407
-------------	---------

Lab Test Name	ALKALINE PHOSPHATASE
---------------	----------------------


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	54
Reported Numeric Result	54
Reference Range low	31
Reference Range high	106
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

Lab Test Name	LDH
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

129

Reported Numeric Result

129

Reference Range low

53

Reference Range high

234

Range Units

U/L

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
-------------	-------

Lab Test Name	SERUM SODIUM
---------------	--------------


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	144
Reported Numeric Result	144
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT16
-------------	-------

Lab Test Name	SERUM POTASSIUM
---------------	-----------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.8
Reported Numeric Result	3.8
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT29
-------------	-------

Lab Test Name	DIRECT BILIRUBIN
---------------	------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT3
-------------	------

Lab Test Name	GGT
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	<hr/>
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Test Status	Done 
-------------	--

Reported Text Result	8
----------------------	---

Reported Numeric Result	8
-------------------------	---

Reference Range low	4
---------------------	---

Reference Range high	49
----------------------	----

Range Units	U/L
-------------	-----

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

SI Numeric Result	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
-------------	--------

Lab Test Name	CREATININE (RATE BLANKED)
---------------	---------------------------


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done 
Reported Text Result	0.6
Reported Numeric Result	0.6
Reference Range low	0.4
Reference Range high	1.1
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT4
-------------	------

Lab Test Name	ALT (SGPT)
---------------	------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT5
-------------	------

Lab Test Name	AST (SGOT)
---------------	------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
-------------	------

Lab Test Name	UREA NITROGEN
---------------	---------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	9
Reported Numeric Result	9
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT10
-------------	-------

Lab Test Name	UR NITRITE
---------------	------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
-------------	------

Lab Test Name	UR SPECIFIC GRAVITY
---------------	---------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	1.007
----------------------	-------

Reported Numeric Result	1.007
-------------------------	-------

Reference Range low	1.003
---------------------	-------

Reference Range high	1.035
----------------------	-------

Range Units	<hr/>
-------------	-------

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/>
----------------	-------

SI Numeric Result	<hr/>
-------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
-------------	------

Lab Test Name	UR PH
---------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	6.5
----------------------	-----

Reported Numeric Result	6.5
-------------------------	-----

Reference Range low	5.0
---------------------	-----

Reference Range high	8.0
----------------------	-----

Range Units	<hr/>
-------------	-------

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/>
----------------	-------

SI Numeric Result	<hr/>
-------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
-------------	-------

Lab Test Name	UR BLOOD
---------------	----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
-------------	-------

Lab Test Name	UR PROTEIN
---------------	------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

Lab Test Name	UR GLUCOSE
---------------	------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

Lab Test Name	UR BILIRUBIN
---------------	--------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	GROUP ORDERED TO COMPLETE VISIT REQUIREMENTS.
--------------------	---

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Cancelled <input checked="" type="radio"/>
Reported Text Result	
Reported Numeric Result	
Reference Range low	
Reference Range high	
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	GROUP ORDERED TO COMPLETE VISIT REQUIREMENTS.
--------------------	---

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Cancelled <input checked="" type="radio"/>
Reported Text Result	
Reported Numeric Result	
Reference Range low	
Reference Range high	
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit Name	DISCHARGE
------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	GROUP ORDERED TO COMPLETE VISIT REQUIREMENTS.
--------------------	---

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Cancelled <input checked="" type="radio"/>
Reported Text Result	
Reported Numeric Result	
Reference Range low	
Reference Range high	
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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (Heart1) 29 Oct 2014 03:07:31

Generated On: 17 Jul 2016 22:26:21

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 03:07:50

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Battery Name	SICAM-1
--------------	---------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:50

Generated On: 17 Jul 2016 22:26:21

Actual Collection Date	2013 09 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

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

Visit ID or Number	DISCHARGE
--------------------	-----------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B264214
--------------	---------

Actual Collection Time	10:43
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

Test ID	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:50

Generated On: 17 Jul 2016 22:26:21

Lab Test Name	SICAM-1-RUO
Test Status	Done <input type="radio"/>
Reported Text Result	193.1
Reported Numeric Result	193.1
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Discharge (Confinement)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 03:07:50

Generated On: 17 Jul 2016 22:26:21

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	6:38
----------------------	------

Time of butt return	6:48
---------------------	------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	8:40
----------------------	------

Time of butt return	8:45
---------------------	------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	9:27
----------------------	------

Time of butt return	9:33
---------------------	------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
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Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	10:27
----------------------	-------

Time of butt return	10:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:15
----------------------	-------

Time of butt return	12:23
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:31
----------------------	-------

Time of butt return	13:39
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:06
----------------------	-------

Time of butt return	15:12
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:56
----------------------	-------

Time of butt return	16:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:49
----------------------	-------

Time of butt return	17:00
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:59
----------------------	-------

Time of butt return	18:07
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:27
----------------------	-------

Time of butt return	19:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:26
----------------------	-------

Time of butt return	20:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:35
----------------------	-------

Time of butt return	21:41
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	20 SEP 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:56
----------------------	-------

Time of butt return	22:04
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	7:02
----------------------	------

Time of butt return	7:12
---------------------	------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	8:09
----------------------	------

Time of butt return	8:19
---------------------	------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556002
-------------------	----------------------

Comment	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	9:22
----------------------	------

Time of butt return	9:31
---------------------	------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:17
----------------------	-------

Time of butt return	10:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	11:23
----------------------	-------

Time of butt return	11:32
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556005
-------------------	----------------------

Comment	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:23
----------------------	-------

Time of butt return	12:33
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	13:22
----------------------	-------

Time of butt return	13:30
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556007
-------------------	----------------------

Comment	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:23
----------------------	-------

Time of butt return	14:35
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:06
----------------------	-------

Time of butt return	15:15
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:58
----------------------	-------

Time of butt return	16:06
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:16
----------------------	-------

Time of butt return	17:24
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	18:14
----------------------	-------

Time of butt return	18:25
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556012
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Comment	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:25
----------------------	-------

Time of butt return	19:35
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556013
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:38
----------------------	-------

Time of butt return	20:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556014
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:19
----------------------	-------

Time of butt return	21:27
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556015
-------------------	----------------------

Comment	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	21 SEP 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:49
----------------------	-------

Time of butt return	21:57
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	184
---------------------	-----

SODIM sample holder number	556
----------------------------	-----

SODIM file number	07TC0184OWN020556016
-------------------	----------------------

Comment	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (Heart1) 29 Oct 2014 03:07:51

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (Heart1) 29 Oct 2014 03:07:58

Generated On: 17 Jul 2016 22:26:21

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (Heart1) 29 Oct 2014 03:07:58

Generated On: 17 Jul 2016 22:26:21

Date of product use DD/MMM/YYYY	19 SEP 2013
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Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Filter kit number	<hr/>
-------------------	-------

Filter vial number	<hr/>
--------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (Heart1) 29 Oct 2014 03:07:58

Generated On: 17 Jul 2016 22:26:21

Comment

Batch Number

B-05775

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-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (1)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (2)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (3)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (4)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (5)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (6)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (7)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (8)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (9)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (10)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (11)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (12)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (13)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (14)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (15)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556001
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (16)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556002
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
---------------------------------	-------------

Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (17)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556003
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (18)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556004
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (19)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556005
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (20)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556006
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (21)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556007
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (22)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556008
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (23)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556009
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (24)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556010
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (25)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556011
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File Status	Accepted 
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Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	29 APR 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (26)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556012
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File Status	Accepted 
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Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	29 APR 2014
---------------------------------	-------------

Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (27)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556013
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File Status	Accepted 
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Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	29 APR 2014
---------------------------------	-------------

Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (28)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556014
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File Status	Accepted 
-------------	--

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	29 APR 2014
---------------------------------	-------------

Operator	Anthony Bruchet 
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Comment	
---------	--

Modified File Number	
----------------------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (29)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556015
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	29 APR 2014
---------------------------------	-------------

Operator	Anthony Bruchet 
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Product Use

Form: Topography files status for mCC (30)

Data signed: (Heart1) 29 Oct 2014 03:07:59

Generated On: 17 Jul 2016 22:26:21

SODIM file number	07TC0184OWN020556016
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	29 APR 2014
---------------------------------	-------------

Operator	Anthony Bruchet 
----------	---

Comment	
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Modified File Number	
----------------------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (Heart1) 29 Oct 2014 03:08:02

Generated On: 17 Jul 2016 22:26:21

Was there any Adverse Event for this subject?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (Heart1) 29 Oct 2014 03:08:02

Generated On: 17 Jul 2016 22:26:21

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder

Data signed: (Heart1) 29 Oct 2014 03:08:02

Generated On: 17 Jul 2016 22:26:21

Were there any events with the device?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (Heart1) 29 Oct 2014 03:08:02

Generated On: 17 Jul 2016 22:26:21

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to Device Type:

THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

If Related to AE, AE Number

Solution Proposed:

If the device was replaced, New Device Serial Number:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (Heart1) 29 Oct 2014 03:08:02

Generated On: 17 Jul 2016 22:26:21

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit

Data signed: (Heart1) 29 Oct 2014 03:08:03

Generated On: 17 Jul 2016 22:26:21

Were there any events with the device?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (Heart1) 29 Oct 2014 03:08:03

Generated On: 17 Jul 2016 22:26:21

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to
Device Type:

THS 2.2 CHARGING UNIT

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

Solution Proposed:

If the device was replaced, New Device Serial Number:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (Heart1) 29 Oct 2014 03:08:03

Generated On: 17 Jul 2016 22:26:21

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)

Data signed: (Heart1) 29 Oct 2014 03:08:03

Generated On: 17 Jul 2016 22:26:21

Device Inventory	1
Log Number	

Date of Device Distribution	19 SEP 2013
DD/MMM/YYYY	

Time of	17:30
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245221
----------------------	---------

Date of Device Collection	21 SEP 2013
DD/MMM/YYYY	

Time of	23:00
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (1)

Data signed: (Heart1) 29 Oct 2014 03:08:04

Generated On: 17 Jul 2016 22:26:21

Device Inventory	1
Log Number	

Date of Device Distribution	19 SEP 2013
DD/MMM/YYYY	

Time of	17:30
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1316621
----------------------	---------

Date of Device Collection	21 SEP 2013
DD/MMM/YYYY	

Time of	23:00
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0064

Form: End of study

Data signed: (Heart1) 29 Oct 2014 03:06:04

Generated On: 17 Jul 2016 22:26:21

End of study date

22 OCT 2013
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:
