

VISIT DATE

» Date of Visit

INFORMED CONSENT

➤ Has the nature of the study been explained to the patient Yes ☐ No ☐
and written informed consent has been obtained?

➤ Date of Signed Informed Consent

INFORMED CONSENT FOR EXPLORATORY GENOMIC

» Has the written exploratory genomic informed consent has been obtained? Yes ☐ No ☐

» Date of Signed Informed Consent

DEMOGRAPHICS

» Age Years
» Height cm
» Weight kg
» BMI kg/m2

MEDICAL/SURGICAL HISTORY

» Any relevant medical and/or surgical history? ☐ Yes ☐ No

Seq. No.	Medical/Surgical History	Start Date	Ongoing	End Date
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PHYSICAL EXAMINATION

Parameter Name	Assessment	Abnormal Finding	Clinically Significant
»» Skin and Mucous	<input type="radio"/> Normal <input type="radio"/> Abnormal	»» <input type="text"/>	»» <input type="radio"/> Yes <input type="radio"/> No
»» Ears/Nose/Throat	<input type="radio"/> Normal <input type="radio"/> Abnormal	»» <input type="text"/>	»» <input type="radio"/> Yes <input type="radio"/> No
»» Pulmonary	<input type="radio"/> Normal <input type="radio"/> Abnormal	»» <input type="text"/>	»» <input type="radio"/> Yes <input type="radio"/> No
»» Cardiac	<input type="radio"/> Normal <input type="radio"/> Abnormal	»» <input type="text"/>	»» <input type="radio"/> Yes <input type="radio"/> No
»» Gastro - intestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal	»» <input type="text"/>	»» <input type="radio"/> Yes <input type="radio"/> No
»» Neurological	<input type="radio"/> Normal <input type="radio"/> Abnormal	»» <input type="text"/>	»» <input type="radio"/> Yes <input type="radio"/> No

HEMATOLOGY

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <input type="button" value="Normal"/> Abnormal NCS Abnormal CS Not Done
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» <input type="button" value="Normal"/> Abnormal NCS Abnormal CS Not Done
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» <input type="button" value="Normal"/> Abnormal NCS Abnormal CS Not Done

Comment

BIOCHEMISTRY

- » Sample Collected? ☐ Yes ☐ No
- » If No, Specify
- » Fasting State ☐ Yes ☐ No ☐ Unknown
- » Date of Collection
- » Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
HbA1c	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Gamma Glutamyl Transferase (GGT)	» <div> < <= > >= </div>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Alkaline Phosphatases (ALP)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride		»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		» <input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	» <input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done

Comments

SEROLOGY

- » Sample Collected? ☐ Yes ☐ No
- » Date of Collection
- » anti-HIV 1 and HIV 2 antibodies ☐ Positive ☐ Negative
- » anti-HCV antibodies ☐ Positive ☐ Negative
- » HBsAg ☐ Positive ☐ Negative

Comments

URINE DRUG SCREENING

- » Sample Collected? ☐ Yes ☐ No
- » Date of Collection
- » Result ☐ Positive ☐ Negative
- » If Positive,
Specify the Positive Drug?

URINARY COTININE» Sample Collected? ☐ Yes ☐ No» Date of Collection » Result ☐ Positive ☐ Negative

Comments

ALCOHOL BREATH TEST» Test Performed? ☐ Yes ☐ No» Date Performed » Result ☐ Positive ☐ Negative

Comments

VITAL SIGNS

- ▶▶ Vitals collected? ☐ Yes ☐ No
- ▶▶ If No, Specify
- ▶▶ Date of measurements
- ▶▶ Body Temperature (°C)
- ▶▶ Result ☐ Normal ☐ Abnormal
- ▶▶ Clinically Significant ☐ Yes ☐ No

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>
2 Mins	<input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>

▶▶ Result ☐ Normal ☐ Abnormal

▶▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG

➤ ECG Performed? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of ECG

➤ Time of ECG

➤ Heart Rate (Beats/min)

➤ PR (ms)

➤ QRS (ms)

➤ QT (ms)

➤ QTcF (ms)

➤ Conclusion Result ☐ Normal ☐ Abnormal

➤ Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
 Relevant Comment

ELIGIBILITY OF SUBJECT

» Are all the inclusion criteria answered Yes? ☐ Yes ☐ No

» If No, please report the inclusion criteria numbers answered as No

Comment

» Are all the Non Inclusion criteria answered No? ☐ Yes ☐ No

» If No, please report the Non Inclusion criteria numbers answered as Yes

Comment

» Is the subject eligible to participate in the study? ☐ Yes ☐ No

» Date of confirmation of eligibility

Comments on

eligibility/non-eligibility

VISIT DATE

➡ Date of Visit

URINE DRUG SCREENING

- » Sample Collected? ☐ Yes ☐ No
- » Date of Collection
- » Result ☐ Positive ☐ Negative
- » If Positive,
Specify the Positive Drug?

URINARY COTININE» Sample Collected? ☐ Yes ☐ No» Date of Collection » Result ☐ Positive ☐ Negative

Comments

ALCOHOL BREATH TEST» Test Performed? ☐ Yes ☐ No» Date Performed » Result ☐ Positive ☐ Negative

Comments

VISIT DATE

➡ Date of Visit

PHYSICAL EXAMINATION (Predose)

Time Point

Pre-dose

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

HEMATOLOGY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

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Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <input type="button" value="Normal"/> Abnormal NCS Abnormal CS Not Done
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» <input type="button" value="Normal"/> Abnormal NCS Abnormal CS Not Done
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» <input type="button" value="Normal"/> Abnormal NCS Abnormal CS Not Done

Comment

BIOCHEMISTRY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	» < <= > >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (PRE DOSE)

Time Point

Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<div> < <= > >= </div>	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

VITAL SIGNS (PRE DOSE)

Time Point Pre-dose

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal

➤ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG (PRE DOSE)

Time Point	Pre-dose
» ECG Performed?	<input type="radio"/> Yes <input type="radio"/> No
» If No, Specify	<input type="text"/>
» Date of ECG	<input type="text"/>
» Time of ECG	<input type="text"/>
» Heart Rate (Beats/min)	<input type="text"/>
» PR (ms)	<input type="text"/>
» QRS (ms)	<input type="text"/>
» QT (ms)	<input type="text"/>
» QTcF (ms)	<input type="text"/>
» Conclusion Result	<input type="radio"/> Normal <input type="radio"/> Abnormal
» Clinically Significant?	<input type="radio"/> Yes <input type="radio"/> No
Abnormality Finding / Relevant Comment	<input type="text"/>

ELIGIBILITY OF SUBJECT

» Are all the inclusion criteria answered Yes? ☐ Yes ☐ No

» If No, please report the inclusion criteria numbers answered as No

Comment

» Are all the Non Inclusion criteria answered No? ☐ Yes ☐ No

» If No, please report the Non Inclusion criteria numbers answered as Yes

Comment

» Is the subject eligible to participate in the study? ☐ Yes ☐ No

» Date of confirmation of eligibility

Comments on

eligibility/non-eligibility

RANDOMIZATION

» Was the subject randomized? ☐ Yes ☐ No

» Date of Randomization

» Food effect cohort ☐ Yes ☐ No

PLACEBO ADMINISTRATION

» Date of Placebo Administration

» Time of Placebo Administration

» Administered Dose (mg)

» Has the Placebo administration been performed according to the protocol? ☐ Yes ☐ No

» If No, please comment

VISIT DATE

➤ Date of Visit

PHYSICAL EXAMINATION (PRE DOSE)

Time Point

Pre-dose

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

HEMATOLOGY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

--

COAGULATION (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comment

BIOCHEMISTRY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	» < <= > >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (PRE DOSE)

Time Point

Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<div> < <= > >= </div>	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST (PRE DOSE)

Time Point

Pre-dose

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done

Comments

VITAL SIGNS (PRE DOSE)

Time Point Pre-dose

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal
 ➤ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

BLOOD SAMPLE FOR EXPLORATORY GENOMIC

<i>Time Point</i>	<i>Sample Collected?</i>	<i>Actual Date & Actual Time</i>
Pre Dose	➡ <input type="radio"/> Yes <input type="radio"/> No	➡ <input type="text"/> ➡ <input type="text"/>

Comment

DRUG ADMINISTRATION

» Date of Study Drug Administration

» Time of Study Drug Administration

» Administered Dose (mg)

» Has the drug administration been performed according to the protocol? ☐ Yes ☐ No

» If No, please comment

VITAL SIGNS (T1 HOUR)

Time Point T1h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>
2 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

VITAL SIGNS (T2 HOUR)

Time Point T2h
 ➤ Vitals collected? ☐ Yes ☐ No
 ➤ If No, Specify
 ➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal
 ➤ Clinically Significant ☐ Yes ☐ No
 Abnormal Finding/
 Relevant Comments

12 LEAD ECG (T2 HOUR)

Time Point

T2h

▶▶ ECG Performed? ☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of ECG

▶▶ Time of ECG

▶▶ Heart Rate (Beats/min)

▶▶ PR (ms)

▶▶ QRS (ms)

▶▶ QT (ms)

▶▶ QTcF (ms)

▶▶ Conclusion Result ☐ Normal ☐ Abnormal

▶▶ Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

VITAL SIGNS (T4 HOUR)

Time Point T4h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>
2 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG (T4 HOUR)

Time Point

T4h

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
Pre Dose	» <input type="radio"/> Yes <input type="radio"/> No		» <input type="text"/> » <input type="text"/>	-60 Mins	» <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
T0h15min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min	
T0h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min	
T0h45min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min	
T1h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5Mins	
T1h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5Mins	
T2h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T2h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T3h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T3h30 min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T4h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	» <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
T6h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T8h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T10h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Min	
T12h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	» <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment	<input type="text"/>				

BLOOD SAMPLE FOR PD

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)
Pre Dose	» <input type="radio"/> Yes <input type="radio"/> No		» <input type="text"/> » <input type="text"/>	- 60 Mins
T0h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min
T1h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T1h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T2h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T3h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T4h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T6h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T8h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T12h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
Comment	<input type="text"/>			

URINE SAMPLE FOR PK & PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
(D-1 pre-dose to D1 T0h) only PD	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
Pre Dose (Only PK)	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>			▶▶ <input type="text"/>	<input type="text"/>
]T0H-T4H]	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
]T4H-T8H]	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
]T8H-T12H]	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
Comment	<input type="text"/>						

VISIT DATE

➡ Date of Visit

HEMATOLOGY (T24 HOUR)

Time Point T24h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION (T24h)

Time Point

T24h

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection (dd-mmm-yyyy)

▶▶ Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
▶▶ Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comment

BIOCHEMISTRY (T24h)

Time Point T24h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	» < <= > >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div><</div><div><=</div><div>></div><div>>=</div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div><</div><div><=</div><div>></div><div>>=</div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div><</div><div><=</div><div>></div><div>>=</div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div><</div><div><=</div><div>></div><div>>=</div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride	»	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (T24h)

Time Point T24h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= > >=	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST (T24h)

Time Point

T24h

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done

Comments

VITAL SIGNS (T24 HOUR)

Time Point T24h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>
2 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG (T24 HOUR)

Time Point

T24h

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

PHYSICAL EXAMINATION (T36h)

Time Point

T36h

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding




» Clinically Significant?

☐ Yes ☐ No

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
T24h	<input type="radio"/> Yes <input type="radio"/> No			+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
T36h	<input type="radio"/> Yes <input type="radio"/> No			+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment					

BLOOD SAMPLE FOR PD

<i>Time Point</i>	<i>Sample Collected?</i>	<i>Schedule Date & Time</i>	<i>Actual Date & Actual Time</i>	<i>Time window (min)</i>
T24h	 <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	 <input type="text"/>  <input type="text"/>	+/- 15 Mins
Comment	<input type="text"/>			

URINE SAMPLE FOR PK & PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
[T12H-T24H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
[T24H-T48H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comment

VISIT DATE

» Date of Visit

VITAL SIGNS (T48 HOUR)

Time Point T48h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate





After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		▶	▶	▶	▶	▶
2 Mins		▶	▶	▶	▶	▶

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
T48h	 <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	 <input type="text"/>  <input type="text"/>	+/- 15 Mins	 <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment	<input type="text"/>				

BLOOD SAMPLE FOR PD

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)
T48h	<input checked="" type="radio"/> Yes <input type="radio"/> No			+/- 15 Mins
Comment				

URINE SAMPLE FOR PK & PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
[T48H-T72H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No						
Comment <input type="text"/>							

VISIT DATE

➡ Date of Visit

VITAL SIGNS (T72 HOUR)

Time Point T72h
 ➤ Vitals collected? ☐ Yes ☐ No
 ➤ If No, Specify
 ➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal
 ➤ Clinically Significant ☐ Yes ☐ No
 Abnormal Finding/
 Relevant Comments

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
T72h	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/> <input type="text"/>	+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment	<input type="text"/>				

BLOOD SAMPLE FOR PD

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)
T72h	<input checked="" type="radio"/> Yes <input type="radio"/> No			+/- 15 Mins
Comment				

URINE SAMPLE FOR PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
[T72H-T96H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No						
Comment <input type="text"/>							

VISIT DATE

» Date of Visit

PHYSICAL EXAMINATION (T96h)

Time Point

T96h

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

HEMATOLOGY (T96 HOUR)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

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Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION (T96h)

Time Point

T96h

» Sample Collected?

☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Comment

BIOCHEMISTRY (T96h)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»					» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»					» Normal Abnormal NCS Abnormal CS Not Done
Urea	»					» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»					» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»					» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»					» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»					» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	»					» Normal Abnormal NCS Abnormal CS Not Done

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 >
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Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Total Bilirubin		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Triglycerides		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (T96h)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<div> < <= > >= </div>	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Micr: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST (T96h)

Time Point

T96h

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comments

VITAL SIGNS (T96 HOUR)

Time Point T96h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		▶	▶	▶	▶	▶
2 Mins		▶	▶	▶	▶	▶

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
 Relevant Comments

12 LEAD ECG (T96 HOUR)

Time Point

T96h

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

VISIT DATE

➡ Date of Visit

PHYSICAL EXAMINATION

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No, specify

» Date Performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

» Weight

 kg

HEMATOLOGY

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION

Sample Collected? ☐ Yes ☐ No

If No, Specify

Date of Collection (dd-mmm-yyyy)

Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div> </div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	<div> </div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	<div> </div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Comment

BIOCHEMISTRY

» Sample Collected? ☐ Yes ☐ No
 » If No, Specify
 » Fasting State ☐ Yes ☐ No ☐ Unknown
 » Date of Collection
 » Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	<input type="text"/> < ≤ > ≥	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alkaline Phosphatases (ALP)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Lactate Dehydrogenase (LDH)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Creatine Phosphokinase (CPK)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Lipase	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Total Bilirubin	»	<input checked="" type="checkbox"/> < <input type="checkbox"/> <= <input type="checkbox"/> > <input type="checkbox"/> >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Conjugated Bilirubin	»	<input checked="" type="checkbox"/> < <input type="checkbox"/> <= <input type="checkbox"/> > <input type="checkbox"/> >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Unconjugated Bilirubin	»	<input checked="" type="checkbox"/> < <input type="checkbox"/> <= <input type="checkbox"/> > <input type="checkbox"/> >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Total Cholesterol	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Triglycerides	»	<input checked="" type="checkbox"/> < <input type="checkbox"/> <= <input type="checkbox"/> > <input type="checkbox"/> >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Sodium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Potassium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Chloride	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done
Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> Abnormal CS <input type="checkbox"/> Not Done

Phosphorus



Normal

Abnormal NCS

Abnormal CS

Not Done

Total Protein



Normal

Abnormal NCS

Abnormal CS

Not Done

Comment

URINALYSIS

Sample Collected? ☐ Yes ☐ No

If No, Specify

Date of Collection

Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Proteins		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Ketones		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Occult Blood		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Bilirubin		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Urobilinogen		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
pH		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Nitrites		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Specific Gravity	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comments

VITAL SIGNS

- ▶▶ Vitals collected? ☐ Yes ☐ No
- ▶▶ If No, Specify
- ▶▶ Date of measurements
- ▶▶ Body Temperature (°C)
- ▶▶ Result ☐ Normal ☐ Abnormal
- ▶▶ Clinically Significant ☐ Yes ☐ No

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>
2 Mins	<input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>

▶▶ Result ☐ Normal ☐ Abnormal

▶▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

STUDY RESTRICTIONS

» Did the subject respect the study restrictions throughout the course of the study? ☐ Yes ☐ No

» If no, Please Clarify

STUDY COMMENTS

Comments

STUDY COMPLETION

» Completion/Discontinuation Date

» Status

- ☐ Completed
- ☐ Adverse Event
- ☐ Lost to Follow-Up
- ☐ Withdrawal by Subject
- ☐ Physician Decision
- ☐ Death
- ☐ Protocol Violation
- ☐ Study Terminated by Sponsor
- ☐ Other

» If Other Specify

VISIT DATE

➡ Date of Visit

URINE DRUG SCREENING

- » Sample Collected? ☐ Yes ☐ No
- » Date of Collection
- » Result ☐ Positive ☐ Negative
- » If Positive,
Specify the Positive Drug?

URINARY COTININE» Sample Collected? ☐ Yes ☐ No» Date of Collection » Result ☐ Positive ☐ Negative

Comments

ALCOHOL BREATH TEST» Test Performed? ☐ Yes ☐ No» Date Performed » Result ☐ Positive ☐ Negative

Comments

VISIT DATE

➡ Date of Visit

PHYSICAL EXAMINATION (Predose)

Time Point

Pre-dose

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

HEMATOLOGY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
»» Lymphocytes	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
»» Monocytes	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
»» Platelet count	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Comment	<div></div>				

COAGULATION (PRE DOSE)

Time Point

Pre-dose

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection (dd-mmm-yyyy)

▶▶ Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
▶▶ Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comment

BIOCHEMISTRY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

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Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (PRE DOSE)

Time Point

Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		» <input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	» <input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Micr: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Micr: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

VITAL SIGNS (PRE DOSE)

Time Point Pre-dose

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal
 ➤ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG (PRE DOSE)

Time Point	Pre-dose
» ECG Performed?	<input type="radio"/> Yes <input type="radio"/> No
» If No, Specify	<input type="text"/>
» Date of ECG	<input type="text"/>
» Time of ECG	<input type="text"/>
» Heart Rate (Beats/min)	<input type="text"/>
» PR (ms)	<input type="text"/>
» QRS (ms)	<input type="text"/>
» QT (ms)	<input type="text"/>
» QTcF (ms)	<input type="text"/>
» Conclusion Result	<input type="radio"/> Normal <input type="radio"/> Abnormal
» Clinically Significant?	<input type="radio"/> Yes <input type="radio"/> No
Abnormality Finding / Relevant Comment	<input type="text"/>

PLACEBO ADMINISTRATION

» Date of Placebo Administration

» Time of Placebo Administration

» Administered Dose (mg)

» Has the Placebo administration been performed according to the protocol? ☐ Yes ☐ No

» If No, please comment

VISIT DATE

➡ Date of Visit

PHYSICAL EXAMINATION (PRE DOSE)

Time Point

Pre-dose

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

HEMATOLOGY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Comment

BIOCHEMISTRY (PRE DOSE)

Time Point Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	» < <= > >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (PRE DOSE)

Time Point

Pre-dose

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= > >=	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

☐ Positive
☐ Negative

☐ Normal
☐ Abnormal NCS
☐ Abnormal CS
☐ Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
»» Micr: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Micr: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Micr: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Micr: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Micr: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
»» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				»» <input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done

Comments

URINE ELECTROLYTES TEST (PRE DOSE)

Time Point

Pre-dose

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done

Comments

VITAL SIGNS (PRE DOSE)

Time Point Pre-dose
Vitals collected? ☐ Yes ☐ No

If No, Specify

Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>
2 Mins	<input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>	➡ <input type="text"/>

Result ☐ Normal ☐ Abnormal
Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

DRUG ADMINISTRATION

» Date of Study Drug Administration

» Time of Study Drug Administration

» Administered Dose (mg)

» Has the drug administration been performed according to the protocol? ☐ Yes ☐ No

» If No, please comment

VITAL SIGNS (T1 HOUR)

Time Point T1h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>
2 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

VITAL SIGNS (T2 HOUR)

Time Point T2h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>
2 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG (T2 HOUR)

Time Point

T2h

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

VITAL SIGNS (T4 HOUR)

Time Point T4h

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal

➤ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
 Relevant Comments

12 LEAD ECG (T4 HOUR)

Time Point

T4h

▶▶ ECG Performed? ☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of ECG

▶▶ Time of ECG

▶▶ Heart Rate (Beats/min)

▶▶ PR (ms)

▶▶ QRS (ms)

▶▶ QT (ms)

▶▶ QTcF (ms)

▶▶ Conclusion Result ☐ Normal ☐ Abnormal

▶▶ Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
Pre Dose	» <input type="radio"/> Yes <input type="radio"/> No		» <input type="text"/> » <input type="text"/>	- 60 Mins	
T0h15min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min	
T0h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min	
T0h45min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min	
T1h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5Mins	
T1h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5Mins	
T2h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T2h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T3h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T3h30 min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T4h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	» <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
T6h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T8h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	
T10h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Min	
T12h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins	» <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment	<input type="text"/>				

BLOOD SAMPLE FOR PD

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)
Pre Dose	» <input type="radio"/> Yes <input type="radio"/> No		» <input type="text"/> » <input type="text"/>	- 60 Mins
T0h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 1 Min
T1h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T1h30min	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T2h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T3h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T4h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T6h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T8h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
T12h	» <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	» <input type="text"/> » <input type="text"/>	+/- 5 Mins
Comment	<input type="text"/>			

URINE SAMPLE FOR PK & PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
(D-1 pre-dose to D1 T0h) only PD	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
Pre Dose (Only PK)	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>			▶▶ <input type="text"/>	<input type="text"/>
]T0H-T4H]	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
]T4H-T8H]	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
]T8H-T12H]	▶▶ <input type="radio"/> Yes <input type="radio"/> No	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	<input type="text"/>
Comment	<input type="text"/>						

MEALS

Meals date

» Breakfast taken? ☐ Yes ☐ No» Breakfast start time » Breakfast end time » Lunch taken? ☐ Yes ☐ No» Lunch start time » Dinner taken? ☐ Yes ☐ No» Dinner start time

Comments

VISIT DATE

➡ Date of Visit

HEMATOLOGY (T24 HOUR)

Time Point T24h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

»» Basophils

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

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COAGULATION (T24h)

Time Point

T24h

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection (dd-mmm-yyyy)

▶▶ Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
▶▶ Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comment

BIOCHEMISTRY (T24h)

Time Point T24h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	» < <= > >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Total Bilirubin		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Triglycerides		<div><</div> <div><=</div> <div>></div> <div>>=</div>	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>		

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (T24h)

Time Point T24h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= > >=	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST (T24h)

Time Point

T24h

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comments

VITAL SIGNS (T24 HOUR)

Time Point T24h

▶ Vitals collected? ☐ Yes ☐ No

▶ If No, Specify

▶ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>
2 Mins	<input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>	▶ <input type="text"/>

▶ Result ☐ Normal ☐ Abnormal

▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG (T24 HOUR)

Time Point

T24h

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

PHYSICAL EXAMINATION (T36h)

Time Point

T36h

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding



» Clinically Significant?

☐ Yes ☐ No

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
T24h	<input type="radio"/> Yes <input type="radio"/> No			+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
T36h	<input type="radio"/> Yes <input type="radio"/> No			+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment					

BLOOD SAMPLE FOR PD

<i>Time Point</i>	<i>Sample Collected?</i>	<i>Schedule Date & Time</i>	<i>Actual Date & Actual Time</i>	<i>Time window (min)</i>
T24h	 <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	 <input type="text"/>  <input type="text"/>	+/- 15 Mins
Comment	<input type="text"/>			

URINE SAMPLE FOR PK & PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
[T12H-T24H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
[T24H-T48H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comment

VISIT DATE

➡ Date of Visit

VITAL SIGNS (T48 HOUR)

Time Point T48h

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate


After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		➤	➤	➤	➤	➤
2 Mins		➤	➤	➤	➤	➤

➤ Result ☐ Normal ☐ Abnormal
 ➤ Clinically Significant ☐ Yes ☐ No
 Abnormal Finding/
 Relevant Comments

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
T48h	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/> <input type="text"/>	+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment	<input type="text"/>				

BLOOD SAMPLE FOR PD

<i>Time Point</i>	<i>Sample Collected?</i>	<i>Schedule Date & Time</i>	<i>Actual Date & Actual Time</i>	<i>Time window (min)</i>
T48h	 <input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	 <input type="text"/>  <input type="text"/>	+/- 15 Mins
Comment	<input type="text"/>			

URINE SAMPLE FOR PK & PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
[T48H-T72H]	<input checked="" type="radio"/> Yes <input type="radio"/> No						
Comment <input type="text"/>							

VISIT DATE

➡ Date of Visit

VITAL SIGNS (T72 HOUR)

Time Point T72h

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal

➤ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
 Relevant Comments

BLOOD SAMPLE FOR PK

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
T72h	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/> <input type="text"/>	+/- 15 Mins	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Comment	<input type="text"/>				

BLOOD SAMPLE FOR PD

Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)
T72h	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			+/- 15 Mins
Comment				

URINE SAMPLE FOR PD

Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g)	Urine vol(ml)
[T72H-T96H]	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No						
Comment <input type="text"/>							

VISIT DATE

» Date of Visit

PHYSICAL EXAMINATION (T96h)

Time Point

T96h

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No,specify

» Date Performed

» Time performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

HEMATOLOGY (T96 HOUR)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Lymphocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Monocytes

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

»» Platelet count

--	--	--	--



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

--

COAGULATION (T96h)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comment

BIOCHEMISTRY (T96h)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Fasting State ☐ Yes ☐ No ☐ Unknown

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	» < <= > >=	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lactate Dehydrogenase (LDH)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Creatine Phosphokinase (CPK)	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Lipase	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>	
Total Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin		»	<div><div></div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>	<div> <div><</div> <div><=</div> <div>></div> <div>>=</div> </div>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride	»	<div><div></div></div>	<div></div>	<div></div>	<div></div>		»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Phosphorus	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Protein	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Comment	<div></div>						

URINALYSIS (T96h)

Time Point T96h

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Proteins		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Ketones		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
pH		»			» Normal Abnormal NCS Abnormal CS Not Done
Nitrites		» <input type="radio"/> Positive <input type="radio"/> Negative			» Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= > >=	»			» Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells

☐ Positive
☐ Negative

Normal
 Abnormal NCS
 Abnormal CS
 Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
»» Micr: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» Normal Abnormal NCS Abnormal CS Not Done
»» Micr: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» Normal Abnormal NCS Abnormal CS Not Done
»» Micr: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» Normal Abnormal NCS Abnormal CS Not Done
»» Micr: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»» Normal Abnormal NCS Abnormal CS Not Done
»» Micr: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				»» Normal Abnormal NCS Abnormal CS Not Done
»» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				»» Normal Abnormal NCS Abnormal CS Not Done
»» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				»» Normal Abnormal NCS Abnormal CS Not Done
»» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				»» Normal Abnormal NCS Abnormal CS Not Done
»» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				»» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST (T96h)

Time Point

T96h

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comments

VITAL SIGNS (T96 HOUR)

Time Point T96h

➤ Vitals collected? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of measurements

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>
2 Mins	<input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>	➤ <input type="text"/>

➤ Result ☐ Normal ☐ Abnormal

➤ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
 Relevant Comments

12 LEAD ECG (T96 HOUR)

Time Point

T96h

» ECG Performed? ☐ Yes ☐ No

» If No, Specify

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

VISIT DATE

➡ Date of Visit

PHYSICAL EXAMINATION

» Did the Physical Examination performed? ☐ Yes ☐ No

» If No, specify

» Date Performed

» Results

☐ Normal ☐ Abnormal

» Abnormal Physical Finding

» Clinically Significant?

☐ Yes ☐ No

» Weight

 kg

HEMATOLOGY

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

»» Basophils	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
»» Lymphocytes	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
»» Monocytes	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
»» Platelet count	<div></div>	<div></div>	<div></div>	<div></div>	<div>»</div> <div> Normal Abnormal NCS Abnormal CS Not Done </div>
Comment	<div></div>				

COAGULATION

» Sample Collected? ☐ Yes ☐ No

» If No, Specify

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
» Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Comment

BIOCHEMISTRY

» Sample Collected? ☐ Yes ☐ No
 » If No, Specify
 » Fasting State ☐ Yes ☐ No ☐ Unknown
 » Date of Collection
 » Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Urea	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	<input type="text"/> < ≤ > ≥	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Alkaline Phosphatases (ALP)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Lactate Dehydrogenase (LDH)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Creatine Phosphokinase (CPK)	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Lipase	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Total Bilirubin	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Conjugated Bilirubin	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Unconjugated Bilirubin	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Total Cholesterol	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Triglycerides	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Sodium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Potassium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Chloride	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>
Calcium	»	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	»	<input type="button" value="Normal"/> <input type="button" value="Abnormal NCS"/> <input type="button" value="Abnormal CS"/> <input type="button" value="Not Done"/>

Phosphorus



Normal
Abnormal NCS
Abnormal CS
Not Done

Total Protein



Normal
Abnormal NCS
Abnormal CS
Not Done

Comment

URINALYSIS

Sample Collected? ☐ Yes ☐ No

If No, Specify

Date of Collection

Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Proteins		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Ketones		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Occult Blood		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Bilirubin		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Urobilinogen		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
pH		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Nitrites		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Specific Gravity	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done

White Blood Cells

» ☐ Positive
☐ Negative

»
Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
» Mic: Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
» Mic: Crystals	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Epithelial Renal Cells	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Bacteria	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done
» Casts	<input type="radio"/> Positive <input type="radio"/> Negative				» Normal Abnormal NCS Abnormal CS Not Done

Comments

URINE ELECTROLYTES TEST

▶▶ Sample Collected?

☐ Yes ☐ No

▶▶ If No, Specify

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
▶▶ Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>
▶▶ Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ <div> Normal Abnormal NCS Abnormal CS Not Done </div>

Comments

VITAL SIGNS

- ▶▶ Vitals collected? ☐ Yes ☐ No
- ▶▶ If No, Specify
- ▶▶ Date of measurements
- ▶▶ Body Temperature (°C)
- ▶▶ Result ☐ Normal ☐ Abnormal
- ▶▶ Clinically Significant ☐ Yes ☐ No

Blood Pressure and Heart Rate

After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins	<input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>
2 Mins	<input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>	▶▶ <input type="text"/>

▶▶ Result ☐ Normal ☐ Abnormal

▶▶ Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

12 LEAD ECG

➤ ECG Performed? ☐ Yes ☐ No

➤ If No, Specify

➤ Date of ECG

➤ Time of ECG

➤ Heart Rate (Beats/min)

➤ PR (ms)

➤ QRS (ms)

➤ QT (ms)

➤ QTcF (ms)

➤ Conclusion Result ☐ Normal ☐ Abnormal

➤ Clinically Significant? ☐ Yes ☐ No

Abnormality Finding / Relevant Comment

STUDY RESTRICTIONS

» Did the subject respect the study restrictions throughout the course of the study? ☐ Yes ☐ No

» If no, Please Clarify

STUDY COMMENTS

Comments

STUDY COMPLETION

» Completion/Discontinuation Date

» Status

- ☐ Completed
- ☐ Adverse Event
- ☐ Lost to Follow-Up
- ☐ Withdrawal by Subject
- ☐ Physician Decision
- ☐ Death
- ☐ Protocol Violation
- ☐ Study Terminated by Sponsor
- ☐ Other

» If Other Specify

PHYSICAL EXAMINATION

- » Did the Physical Examination performed? ☐ Yes ☐ No
- » Date Performed
- » Results ☐ Normal ☐ Abnormal
- » Abnormal Physical Finding
- » Clinically Significant? ☐ Yes ☐ No

HEMATOLOGY

» Sample Collected? ☐ Yes ☐ No

» Date of Collection

» Time of Collection

Parameter Name	Result	Unit	LLN	ULN	Assessment
Red Blood Cells (RBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Hematocrit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Mean Corpuscular Volume (MCV)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Mean Corpuscular Hemoglobin (MCH)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Mean Corpuscular Hemoglobin Concentration (MCHC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
White Blood Cells (WBC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Neutrophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
Eosinophils	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Basophils	<div></div>	<div></div>	<div></div>	<div></div>	<div>»<div>Normal Abnormal NCS Abnormal CS Not Done</div></div>
Lymphocytes	<div></div>	<div></div>	<div></div>	<div></div>	<div>»<div>Normal Abnormal NCS Abnormal CS Not Done</div></div>
Monocytes	<div></div>	<div></div>	<div></div>	<div></div>	<div>»<div>Normal Abnormal NCS Abnormal CS Not Done</div></div>
Platelet count	<div></div>	<div></div>	<div></div>	<div></div>	<div>»<div>Normal Abnormal NCS Abnormal CS Not Done</div></div>
Comment	<div></div>				

BIOCHEMISTRY

▶▶ Sample Collected? ☐ Yes ☐ No

▶▶ Fasting State ☐ Yes ☐ No ☐ Unknown

▶▶ Date of Collection

▶▶ Time of Collection

Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Creatinine		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Urea		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	<input type="text"/> < ≤ > ≥	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done
Alkaline Phosphatases (ALP)		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	▶▶ Normal Abnormal NCS Abnormal CS Not Done

Lactate Dehydrogenase (LDH)					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Creatine Phosphokinase (CPK)					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Lipase					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Bilirubin	<div><</div> <div><=</div> <div>></div> <div>>=</div>				»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Conjugated Bilirubin	<div><</div> <div><=</div> <div>></div> <div>>=</div>				»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Unconjugated Bilirubin	<div><</div> <div><=</div> <div>></div> <div>>=</div>				»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Total Cholesterol					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Triglycerides	<div><</div> <div><=</div> <div>></div> <div>>=</div>				»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Sodium					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Potassium					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Chloride					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>
Calcium					»	<div>Normal</div> <div>Abnormal NCS</div> <div>Abnormal CS</div> <div>Not Done</div>

Phosphorus



- Normal
- Abnormal NCS
- Abnormal CS
- Not Done

Total Protein



- Normal
- Abnormal NCS
- Abnormal CS
- Not Done

Comment

URINALYSIS

Sample Collected? ☐ Yes ☐ No

Date of Collection

Time of Collection

Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Proteins		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Ketones		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Occult Blood		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Bilirubin		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Urobilinogen		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
pH		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Nitrites		<input type="radio"/> Positive <input type="radio"/> Negative			<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done
Specific Gravity	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal NCS <input type="radio"/> Abnormal CS <input type="radio"/> Not Done

White Blood Cells

- ☐ Positive
☐ Negative



Normal
Abnormal NCS
Abnormal CS
Not Done

Comments

MICROSCOPIC RESULTS

Parameter Name	Results	Units	LLN	ULN	Assessment
Micr: Glucose	<div></div>	<div></div>	<div></div>	<div></div>	<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Micr: Protein	<div></div>	<div></div>	<div></div>	<div></div>	<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Micr: Red Blood Cells	<div></div>	<div></div>	<div></div>	<div></div>	<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Micr: White Blood Cells	<div></div>	<div></div>	<div></div>	<div></div>	<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Micr: Crystals	<div><div></div>Positive <div></div>Negative</div>				<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Epithelial Cells	<div><div></div>Positive <div></div>Negative</div>				<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Epithelial Renal Cells	<div><div></div>Positive <div></div>Negative</div>				<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Bacteria	<div><div></div>Positive <div></div>Negative</div>				<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>
Casts	<div><div></div>Positive <div></div>Negative</div>				<div><div></div>Normal Abnormal NCS Abnormal CS Not Done</div>

Comments

URINE ELECTROLYTES TEST

Sample Collected? ☐ Yes ☐ No
 Date of Collection
 Time of Collection

Parameter Name	Results	Units	LLN	ULN	Assessment
Calcium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Normal Abnormal NCS Abnormal CS Not Done
Sodium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Normal Abnormal NCS Abnormal CS Not Done
Potassium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Normal Abnormal NCS Abnormal CS Not Done
Chloride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Normal Abnormal NCS Abnormal CS Not Done

Comments

COAGULATION

» Sample Collected? ☐ Yes ☐ No

» Date of Collection (dd-mmm-yyyy)

» Time of Collection (hh:mm)

Parameter Name	Result	Unit	LLN	ULN	Assessment
Prothrombin time (PT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
International normalized ratio (INR)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done
aPTT(ratio)	<input type="text"/>		<input type="text"/>	<input type="text"/>	» Normal Abnormal NCS Abnormal CS Not Done

Comment

12 LEAD ECG

» ECG Performed? ☐ Yes ☐ No

» Date of ECG

» Time of ECG

» Heart Rate (Beats/min)

» PR (ms)

» QRS (ms)

» QT (ms)

» QTcF (ms)

» Conclusion Result ☐ Normal ☐ Abnormal

» Clinically Significant? ☐ Yes ☐ No

Abnormality Finding /
Relevant Comment

VITAL SIGNS

- » Vitals collected? ☐ Yes ☐ No
- » Date of measurements
- » Body Temperature (°C)
- » Result ☐ Normal ☐ Abnormal
- » Clinically Significant ☐ Yes ☐ No

Blood Pressure and Heart Rate

- | After | Position | Actual Time Position
(hh:mm) | Actual Time Measurement
(hh:mm) | Systolic
(mmHg) | Diastolic
(mmHg) | Heart rate
(bpm) |
|---------|----------------------|---------------------------------|------------------------------------|------------------------|------------------------|------------------------|
| 10 Mins | <input type="text"/> | » <input type="text"/> | » <input type="text"/> | » <input type="text"/> | » <input type="text"/> | » <input type="text"/> |
| 2 Mins | <input type="text"/> | » <input type="text"/> | » <input type="text"/> | » <input type="text"/> | » <input type="text"/> | » <input type="text"/> |
- » Result ☐ Normal ☐ Abnormal
- » Clinically Significant ☐ Yes ☐ No

Abnormal Finding/
Relevant Comments

MEDICAL / SURGICAL HISTORY

» Seq. No. _____

» Medical/Surgical History

SOC	<input type="text"/>	<input type="text"/>
HLGT	<input type="text"/>	<input type="text"/>
HLT	<input type="text"/>	<input type="text"/>
PT	<input type="text"/>	<input type="text"/>
LLT	<input type="text"/>	<input type="text"/>

» Start Date

» Ongoing

☐ Yes
 ☐ No

» End Date

PRIOR/CONCOMITANT MEDICATION

Medication No.

Taken Prior to Study? ☐ Yes ☐ No

Medication Name

WhoDD

Product name	
Medicinal product Id	
Drug code	
Preferred base name	
Preferred salt name	
Product type	
Generic/Preferred	
Pharmaceutical form	Ingredient(s)
Strength	
Country	
MAH	
Company	
Name source	
ATC code(s)	

Indication

Start Date

Ongoing

☐ Yes ☐ No

End Date

Dose

Unit

mg
ug
mL
g
IU
Other

If other, specify

Route

Oral
Cutaneous
Subcutaneous
Transdermal
Intraocular
Intramuscular
Respiratory (Inhalation)
Intralesional
Intraperitoneal
Nasal
Vaginal
Rectal
Injectable
Intravenous
Intradermal
Intra-arterial
Epidural
Pulmonary
Auricular
Sublingual
Ocular
Intrauterine
Other

If other, specify

► Frequency

OAD
BID
TID
QID
QOD
QM
PRN
QD
Unknown
Other

► If other, specify

AE Number

Please enter the AE number if the CM is given for an AE

ADVERSE EVENT

▶▶ Adverse Event Number

▶▶ Adverse Event

MedDRA SOC

HLGT

HLT

PT

LLT

▶▶ Start Date ▶▶ Start Time

▶▶ End Date ▶▶ End Time

▶▶ Severity ☐ Mild ☐ Moderate ☐ Severe

▶▶ Serious ☐ Yes ☐ No

▶▶ Congenital Anomaly or Birth Defect ☐ Yes ☐ No

▶▶ Significant Disability ☐ Yes ☐ No

▶▶ Death ☐ Yes ☐ No

▶▶ Life Threatening ☐ Yes ☐ No

▶▶ Other Medically Important Event ☐ Yes ☐ No

▶▶ Hospitalization/Prolonged ☐ Yes ☐ No

▶▶ Date of Hospitalization

▶▶ Relationship to Study Treatment ☐ Probable ☐ Possible ☐ Unlikely ☐ Unrelated ☐ Not Assessable

▶▶ Outcome ☐ Recovered/Resolved ☐ Recovering/Resolving ☐ Recovered/Resolved with Sequelae ☐ Not Recovered/Not Resolved ☐ Fatal ☐ Unknown

▶▶ Action Taken with Study Treatment ☐ Dose Not Changed ☐ Drug Interrupted ☐ Drug Withdrawn ☐ Not Applicable ☐ Unknown

▶▶ Other Action ☐ Yes ☐ No

▶▶ If Yes, Specify

▶▶ Any relevant concomitant medication recorded? ☐ Yes ☐ No