



Visit Date | VISITDAT

Day | VISITDATD Month | VISITDATM Year | VISITDATY

D	D	M	M	M	Y	Y	Y	Y
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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was informed consent taken? | IFCYN

- ☐ Yes
- ☐ No

Reason for not taken | IFCREASN

Reason for not taken inform consent

Informed Consent Date | DSSTDAT

Day | DSSTDATD

Month | DSSTDATM

Year | DSSTDATY

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Informed Consent Time | DSSTTIM

Hour | DSSTTIMH

Minute || DSSTTIMM

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Informed Consent form Version | ICFVER

Enter Informed Consent Version

Date of eligibility assessment | INCDAT

Day | INCDATD

Month | INCDATM

Year | INCDATY

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Y

Inclusion Criteria:

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
1. Subject has signed an Informed Consent Form (ICF) prior to any study-specific procedures being performed	☐	☐	☐
2. ≥ 18 years old, irrespective of their race and ethnicity.	☐	☐	☐
3. Body Mass Index (BMI) 18.0-40.0 kg/m2, inclusive, at screening.	☐	☐	☐
4. Participants are willing and able to adhere to study protocol requirements and restrictions including but not limited to scheduled outpatient visits, inpatient stay, laboratory tests, and 12-lead ECGs.	☐	☐	☐

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
5. A. Diagnosis of RA and meeting the 2010 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria for RA at least 3 months prior to screening AND Active disease defined by ≥ 6 tender out of 68 joints and ≥ 6 swollen out of 66 swollen joint count at both screening and Day 1. AND Participants received csDMARD therapy for ≥ 3 months and on a stable dose for ≥ 4 weeks prior to the first dose of study drug. The csDMARD allowed include MTX ($\leq 25\text{mg/week}$), sulfasalazine (3 grams a day), hydroxychloroquine ($\leq 400\text{mg/day}$), chloroquine ($\leq 250\text{mg/day}$), and leflunomide ($\leq 20\text{mg/day}$) or intolerance to csDMARD as assessed by the investigator.	☐	☐	☐
5. B. PsA diagnosis of at least 3 months duration prior to the date of first screening with Classification of Psoriatic Arthritis (CASPAR) confirmed diagnosis at Screening. Have active psoriasis defined by at least 1 psoriasis lesion ≥ 2 cm diameter in areas other than the axilla or groin, or nail changes consistent with psoriasis or a documented history of plaque psoriasis. AND Active disease defined by ≥ 3 tender out of 68 joints and ≥ 3 swollen out of 66 swollen joint count at both screening and Day 1. AND Participants received standard doses of NSAIDS for ≥ 4 weeks and/or csDMARDS (MTX ($\leq 25\text{mg/week}$), sulfasalazine (3 grams a day), and leflunomide ($\leq 20\text{mg/day}$), administered for ≥ 3 months and on a stable dose for ≥ 4 weeks prior to the first dose of study drug or intolerance to NSAIDS or csDMARDS as assessed by the investigator. Other DMARDS that are not listed as a prohibited concomitant medication may be considered after discussion with the Study physician.	☐	☐	☐

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
6. The subject must be judged to be in good health by the investigator to participate in the study, based on clinical evaluations, including laboratory safety tests, medical history, physical examination, vital signs and 12-lead ECG completed at the screening visit and prior to the first dose of study drug.	☐	☐	☐
7. Female subject is postmenopausal (at least 1 year; to be confirmed by FSH if less than 2 years since last menstrual period), permanently sterilized (e.g. tubal occlusion, hysterectomy, bilateral salpingectomy) or if of childbearing potential and engaged in sexual activity that can result in pregnancy must agree to use any two of the highly effective contraception methods listed below. Male participants with a partner of childbearing potential must also agree to use any two of the highly effective contraception methods listed below between them and their partner. This criterion must be followed from screening visit to 6 weeks after the last dose in females and for 90 days after the last dose for males.	☐	☐	☐
a. The following applies to all female participants with childbearing potential and female partners of male participants enrolled in the study. i. Implantable progestogen-only hormone contraception associated with inhibition of ovulation. ii. Intrauterine device. iii. Intrauterine hormone-releasing system. iv. Bilateral tubal occlusion. v. Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation: a. Oral b. Intravaginal c. Transdermal d. Injectable vi. Progestogen-only hormone contraception (oral or injectable) associated with inhibition of ovulation.			

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
vii. Vasectomized partner viii. Sexual abstinence -this is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention. The reliability of sexual abstinence needs to be evaluated about the duration of the study and the preferred and usual lifestyle of the participant. ix. A combination of male condoms with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods) b. The following applies to all male participants in the study: i. Sexual abstinence- this is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention. The reliability of sexual abstinence must be evaluated for the study and the participant's preferred and usual lifestyle. ii. A combination of male condoms with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods). iii. Vasectomy			
8. Negative serum B-human chorionic gonadotropin test at screening (for all females) and negative urine pregnancy at randomization (Day 1) (females of childbearing potential) prior to administration of investigational product.	☐	☐	☐

Exclusion Criteria

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
1. History of clinically significant medical conditions or any other reason that in the opinion of the PI would interfere with subject's participation in this study	☐	☐	☐
2. History of clinically significant drug or alcohol abuse per the PI's opinion within the last 6 months.	☐	☐	☐
3. Pregnant or lactating women or women currently undergoing infertility treatments or women who intend to become pregnant during the time of study or for 6 weeks after last dose.	☐	☐	☐
4. Any known history of malignancy within 5 years other than completely treated non-metastatic basal cell carcinomas or squamous cell carcinomas of the skin or localized carcinoma in situ of the cervix.	☐	☐	☐
5. Any known history of a rheumatologic, autoimmune or cutaneous disease other than RA (except secondary Sjögren's syndrome), or psoriatic arthritis that could confound the assessments.	☐	☐	☐
6. Significant systemic involvement secondary to RA/PsA (active vasculitis, pulmonary fibrosis, or Felty's syndrome).	☐	☐	☐
7. Currently have non-plaque forms of psoriasis eg erythrodermic, guttate or pustular with the exception of nail psoriasis which is allowed.	☐	☐	☐
8. Receipt of an investigational therapy less than 3 months or 5 drug-elimination half-lives (whichever is longer) prior to first administration of study treatment and during the study	☐	☐	☐

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
9. Receipt of any of the following excluded therapies: Any cell depleting therapy, anti-CD4, anti-CD5, anti-CD3 other than anti-CD20 such as rituximab, ocrelizumab, and ofatumumab. Patients who have received rituximab or other selective B lymphocyte depleting agents (including experimental agents) are eligible if they have not received such therapy for at least 1 year prior to study baseline Have received prior tsDMARDs including but not limited to inhibitors of Janus kinase (JAK), Bruton tyrosine kinase, or tyrosine kinase 2, including baricitinib, tofacitinib, upadacitinib, filgotinib, ibrutinib, fenebrutinib, or apremilast in past month prior to screening or 5 drug elimination half-lives (whichever is longer) and throughout the study. Have received prior immunomodulatory bDMARDs including, but not limited to ustekinumab, secukinumab, abatacept, belimumab, anifrolumab within 4 weeks or 5 drug elimination half-lives whichever is longer and throughout the study. Receipt of any other DMARDs (not allowed per inclusion criterion 5) within less than 5 half-lives, prior to screening visit and throughout the study.	☐	☐	☐
10. Lack of response to ≥ 1 therapeutic agent targeting tumor necrosis factor or IL-6, or lack of response to > 2 bDMARDs (regardless of whether targeting different MOA or not).	☐	☐	☐
11. Use of psoriasis treatments: a. Oral or topical retinoids 2 weeks prior to Day 1 and throughout the study b. Topical treatments (steroids, or JAK inhibitors) within 2 weeks prior to Day 1 and throughout the study c. PUVA or UVB phototherapy within 4 weeks prior to Day 1 and throughout the study.	☐	☐	☐
12. No high potency opioid analgesics 2 weeks prior to baseline and during study. Analgesic dose must remain stable throughout from screening through completion of	☐	☐	☐

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
the study.			
13. Subject has clinical or laboratory evidence of active or latent TB infection at screening as assessed by QuantiFERON-TB-Gold or a purified protein derivative skin test or equivalent (or both if required per local guidelines) and chest X-ray. Chest X-rays taken within 2 months prior to screening may be used instead of during screening if there is documentation showing no evidence of infection or malignancy as read by qualified physician.	☐	☐	☐
14. Any active or recurrent infection within the past 4 weeks prior to screening requiring IV or oral antibiotics.	☐	☐	☐
15. Laboratory values of the following at the Screening Visit: Hemoglobin < 9 g/dL for males and < 8.5 g/dL for females WBC <3.5X10 ⁹ /L Absolute neutrophil count (ANC) < 1500 cells/μL , (or < 1200 cells/μL for participants of African descent who are black) Aspartate aminotransferase or alanine aminotransferase > 2.0 x the upper limit of normal (ULN) or bilirubin >= ULN; Bilirubin >ULN Platelets < 100,000 cells/[mm ³] (10 ⁹ /L); Clinically significant abnormal screening laboratory results as evaluated by the Investigator	☐	☐	☐
16. Acutely worsened renal function within past 3 months prior to screening or estimated GFR by CDK-EPI creatinine equation with adjustment for body surface area <60ml/min.	☐	☐	☐
17. Participants with a history of active or latent TB will be excluded from the study, unless documentation of complete TB treatment, consistent with local country	☐	☐	☐

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
guidelines, can be provided.			
18. Subject has any clinically significant finding on 12-lead ECG at screening or admission. NOTE: QTc(F) interval of >450 msec in male participants or >470 msec in female participants will be the basis for exclusion from the study. ECG may be repeated once for confirmatory purposes if initial values obtained exceed the limits specified.	☐	☐	☐
19. Subject with positive results for HBsAg (hepatitis B surface antigens) and/or HBcAb (Hepatitis B core antibodies) and/or HCV Ab (hepatitis C antibodies) confirmed by HCV RNA, and/or HIV Ab (human immunodeficiency virus antibodies).	☐	☐	☐
20. Blood loss of >250 mL or donated blood within 56 days or donated plasma within 7 days of screening.	☐	☐	☐
21. Recent vaccination with live attenuated vaccines such as influenza, MMR, Herpes zoster, varicella, yellow fever, Rotavirus vaccine, etc., or inactivated vaccines such as Hepatitis A, rabies vaccine, etc. 30 days prior to screening visit	☐	☐	☐
22. History of infection 1) requiring hospitalization or parenteral antimicrobial therapy within 3 months prior to Day 1 or 2) treated with oral antimicrobial therapy within 2 weeks prior to Day 1.	☐	☐	☐
23. Subject is investigative site personnel, sponsor personnel, or a member of their immediate families (spouse, parent, child or sibling whether biological or legally adopted).	☐	☐	☐

Any medical history experienced? | MHYN

- ☐ Yes
☐ No

Medical History Identifier | MHNUM

Enter Medical History Identifier

Category for Medical History | MHCAT

- ☐ Medical History
☐ Surgical History

Reported Term for the Medical History | MHTERM

Enter Reported Term for the Medical History

Medical History Event Start Date | MHSTDAT

Day | MHSTDATD

Month | MHSTDATM

Year | MHSTDATY

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Ongoing Medical History Event | MHONGO

- ☐ Yes
☐ No

Medical History Event End Date | MHENDAT

Day | MHENDATD

Month | MHENDATM

Year | MHENDATY

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Y

Is the subject taking any medication? | MHCONMED

- ☐ Yes
☐ No

Any medical history experienced? | MHYN

- ☐ Yes
☐ No

Medical History Identifier | MHNUM

Enter Medical History Identifier

Category for Medical History | MHCAT

- ☐ Medical History
☐ Surgical History

Reported Term for the Medical History | MHTERM

Enter Reported Term for the Medical History

Medical History Event Start Date | MHSTDAT

Day | MHSTDATD

Month | MHSTDATM

Year | MHSTDATY

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Ongoing Medical History Event | MHONGO

- ☐ Yes
☐ No

Medical History Event End Date | MHENDAT

Day | MHENDATD

Month | MHENDATM

Year | MHENDATY

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Is the subject taking any medication? | MHCONMED

- ☐ Yes
☐ No

Was body height measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body height measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

D

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M

Y

Y

Y

Y

Height | HEIGHT

Enter Height

Height Unit | HEIGHTU

Enter Custom Unit

Was body weight measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body weight measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

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Y

Weight | WEIGHT

Enter Weight

Weight Unit | WEIGHTU

Enter Custom Unit

Body Mass Index | BMI

BMI

BMI Unit | BMIU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Screen for infectious diseases

Examination Test or Examination Name	Remark
HIV AB	Remark
Hepatitis B-surface Antigen(HBsAg)	Remark
Hepatitis C Virus AB	Remark

Was QuantiFeron TB Gold test performed? | TBYN

- ☐ Yes
- ☐ No

Reason Test Not Done | LBREASND

Enter Reason Test Not Done

Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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QuantiFeron TB Gold Result | LBTEST

- ☐ Positive
- ☐ Negative
- ☐ Indeterminate

Was a PPD Skin Test Performed? | PPDYN

- ☐ Yes
☐ No

Date of PPD | PPDDAT

Day PPDDATD		Month PPDDATM			Year PPDDATY			
D	D	M	M	M	Y	Y	Y	Y

Erythema Present? | ERYYN

- ☐ Yes
☐ No

Erythema Measurement (in mm) | ERYTHEMA

Enter Erythema Measurement (in mm)

Result Interpretation | ERYRES

- ☐ Positive
☐ Negative
☐ Indeterminate

Was a Chest X-Ray Performed? | XRAYYN

- ☐ Yes
- ☐ No

Date of Chest X-Ray | XRAYDAT

Day | XRAYDATD

Month | XRAYDATM

Year | XRAYDATY

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Y

Y

Were there any abnormal findings? | XRAYRES

- ☐ Normal
- ☐ Abnormal, Clinically not significant
- ☐ Abnormal, Clinically significant



Was Alcohol test performed? | AYN

- ☐ Yes
- ☐ No

Alcohol Sample Collection date | LBDAT1

Day | LBDAT1D

Month | LBDAT1M

Year | LBDAT1Y

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Y

Y

Y

Alcohol test result | ACLO

- ☐ Positive
- ☐ Negative

Was the drug screening test performed? | DYN

- ☐ Yes
- ☐ No

Drug Sample Collection date | LBDAT2

Day | LBDAT2D

Month | LBDAT2M

Year | LBDAT2Y

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Y

Y

Y

Drug screening test result | DRUG

- ☐ Positive
- ☐ Negative

Was physical examination performed? | PEYN

☐ Yes

☐ No

Physical Examination Date | PEDAT

Day | PEDATD Month | PEDATM Year | PEDATY

D	D	M	M	M	Y	Y	Y	Y
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Physical Examination Time | PETIM

Hour | PETIMH Minute | PETIMM

H	H	M	M
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Physical Examination Tests

Examination Test or Examination Name	Remark
General Appearance	Remark
Skin/ dermatological	Remark
Head, Ears, Eyes, Nose, and Throat Examination	Remark
Neck/ Thyroid	Remark
Lymphatic	Remark
Cardiovascular	Remark
Respiratory	Remark
Abdomen	Remark
Genitourinary	Remark
Nervous System	Remark

Examination Test or Examination Name	Remark
Musculoskeletal	Remark
Gastrointestinal	Remark
Extremities	Remark
Psychiatric disorders	Remark

Comment | PECOM

Enter comment if any

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment



Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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D

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Month | LBDATM

Year | LBDATY

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

H

H

Minute | LBTIMM

M

M

High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Anti-CCP antibodies test assessed? | ACCPYN

- ☐ Yes
☐ No

Reason for not done | LBREASND

Enter Reason for not done

Sample Collected Date | COLLDAT

Day | COLLDATD

Month | COLLDATM

Year | COLLDATY

D

D

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M

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Y

Y

Anti-CCP Level | ANTCCPP

Enter Anti-CCP Level

Unit | ANTCPPU

Enter Custom Unit

Reference Range | LBNRIND

- ☐ Normal
☐ Abnormal, clinically not significant
☐ Abnormal, clinically significant

Rheumatoid Factor | RFACTOR

- ☐ Positive
☐ Negative

Was Serum Pregnancy Test sample collected? | PREGYN

- ☐ Yes
- ☐ No

Reason Test Not Done | LBREASND

Enter Reason Test Not Done

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

H

H

M

M

Serum Beta HCG | LBTEST

- ☐ Positive
- ☐ Negative
- ☐ Valid Result Not Obtained

Was FSH Test sample collected? | FSHYN

- ☐ Yes
☐ No

Reason Test Not Done | LBREASND

Enter Reason Test Not Done

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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D

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M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

H

H

M

M

FSH Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Follicle-stimulating hormone	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Follicle-stimulating hormone	☐	☐	☐	☐	Remark

Was the Specimen sample collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

H

H

M

M

Urine Analysis Tests

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
pH	☐	☐	☐	☐	Remark
Specific gravity	☐	☐	☐	☐	Remark
Urine Micro - WBC	☐	☐	☐	☐	Remark
Urine Micro - RBC	☐	☐	☐	☐	Remark
Urine Micro - Cast	☐	☐	☐	☐	Remark
Urine Micro - Crystals	☐	☐	☐	☐	Remark
Urine Micro - Bacteria	☐	☐	☐	☐	Remark
Urine Micro - Yeast	☐	☐	☐	☐	Remark
Urine Micro - Parasites	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Protein	☐	☐	☐	☐	Remark
Glucose	☐	☐	☐	☐	Remark
Blood	☐	☐	☐	☐	Remark
Nitrite	☐	☐	☐	☐	Remark
Leucocytes	☐	☐	☐	☐	Remark
Ketones	☐	☐	☐	☐	Remark
Bilirubin	☐	☐	☐	☐	Remark
Color/appearance	☐	☐	☐	☐	Remark
Urobilinogen	☐	☐	☐	☐	Remark

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation



Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGC

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
- ☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD Day		QSDATM Month			QSDATY Year			
D	D	M	M	M	Y	Y	Y	Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right								
Tender			Swelling					Tender			Swelling					
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA		
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐						
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	☐	



Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0

Was HAQ - Disability Index assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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D

M

M

M

Y

Y

Y

Y

Health Assessment Questionnaire-Disability Index score

In this section we are interested in learning how your illness affects your ability to function in daily life.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
- Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
- Stand up from a straight chair?	☐	☐	☐	☐
- Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
- Cut your meat?	☐	☐	☐	☐

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
- Lift a full cup or glass to your mouth?	☐	☐	☐	☐
- Open a new milk carton?	☐	☐	☐	☐
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Dressing and Grooming
- ☐ Arising
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Eating
- ☐ Walking

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
HYGIENE				
Are you able to:				

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
- Wash and dry your body?	☐	☐	☐	☐
- Take a tub bath?	☐	☐	☐	☐
- Get on and off the toilet?	☐	☐	☐	☐
REACH				
Are you able to:				
- Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
- Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
- Open car doors?	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
- Run errands and shop?	☐	☐	☐	☐
- Get in and out of a car?	☐	☐	☐	☐
- Do chores such as vacuuming or yardwork?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Raised toilet seat
- ☐ Bathtub seat
- ☐ Jar opener (for jars previously opened)
- ☐ Bathtub bar
- ☐ Long-handled appliances for reach
- ☐ Long-handled appliances in bathroom

☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

☐ Hygiene

☐ Reach

☐ Gripping and opening things

☐ Errands and chores



Was Patient's Arthritis Pain Assessed? | QAYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Y

Pain Intensity



Was Patient Global Assessment of Disease Activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Disease Activity Score





Was Physician Global Assessment of disease activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Disease Activity Score



Was Psoriasis Area and Severity Index assessed? | PASIYN

- ☐ Yes
- ☐ No
- ☐ NA

Reason for not done? | PASIREAND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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D

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Y

Y

Y

Y

Assessment time | PASITIM

Hour | PASITIMH

Minute | PASITIMM

H

H

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M

Psoriasis Area and Severity Index

	Head
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Trunk
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Legs
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Date of eligibility assessment | INCDAT

Day | INCDATD

Month | INCDATM

Year | INCDATY

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Y

Inclusion Criteria:

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
1. Subject has signed an Informed Consent Form (ICF) prior to any study-specific procedures being performed	☐	☐	☐
2. ≥ 18 years old, irrespective of their race and ethnicity.	☐	☐	☐
3. Body Mass Index (BMI) 18.0-40.0 kg/m2, inclusive, at screening.	☐	☐	☐
4. Participants are willing and able to adhere to study protocol requirements and restrictions including but not limited to scheduled outpatient visits, inpatient stay, laboratory tests, and 12-lead ECGs.	☐	☐	☐

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
5. A. Diagnosis of RA and meeting the 2010 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria for RA at least 3 months prior to screening AND Active disease defined by ≥ 6 tender out of 68 joints and ≥ 6 swollen out of 66 swollen joint count at both screening and Day 1. AND Participants received csDMARD therapy for ≥ 3 months and on a stable dose for ≥ 4 weeks prior to the first dose of study drug. The csDMARD allowed include MTX ($\leq 25\text{mg/week}$), sulfasalazine (3 grams a day), hydroxychloroquine ($\leq 400\text{mg/day}$), chloroquine ($\leq 250\text{mg/day}$), and leflunomide ($\leq 20\text{mg/day}$) or intolerance to csDMARD as assessed by the investigator.	☐	☐	☐
5. B. PsA diagnosis of at least 3 months duration prior to the date of first screening with Classification of Psoriatic Arthritis (CASPAR) confirmed diagnosis at Screening. Have active psoriasis defined by at least 1 psoriasis lesion ≥ 2 cm diameter in areas other than the axilla or groin, or nail changes consistent with psoriasis or a documented history of plaque psoriasis. AND Active disease defined by ≥ 3 tender out of 68 joints and ≥ 3 swollen out of 66 swollen joint count at both screening and Day 1. AND Participants received standard doses of NSAIDS for ≥ 4 weeks and/or csDMARDS (MTX ($\leq 25\text{mg/week}$), sulfasalazine (3 grams a day), and leflunomide ($\leq 20\text{mg/day}$), administered for ≥ 3 months and on a stable dose for ≥ 4 weeks prior to the first dose of study drug or intolerance to NSAIDS or csDMARDS as assessed by the investigator. Other DMARDS that are not listed as a prohibited concomitant medication may be considered after discussion with the Study physician.	☐	☐	☐

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
6. The subject must be judged to be in good health by the investigator to participate in the study, based on clinical evaluations, including laboratory safety tests, medical history, physical examination, vital signs and 12-lead ECG completed at the screening visit and prior to the first dose of study drug.	☐	☐	☐
7. Female subject is postmenopausal (at least 1 year; to be confirmed by FSH if less than 2 years since last menstrual period), permanently sterilized (e.g. tubal occlusion, hysterectomy, bilateral salpingectomy) or if of childbearing potential and engaged in sexual activity that can result in pregnancy must agree to use any two of the highly effective contraception methods listed below. Male participants with a partner of childbearing potential must also agree to use any two of the highly effective contraception methods listed below between them and their partner. This criterion must be followed from screening visit to 6 weeks after the last dose in females and for 90 days after the last dose for males.	☐	☐	☐
a. The following applies to all female participants with childbearing potential and female partners of male participants enrolled in the study.			
i. Implantable progestogen-only hormone contraception associated with inhibition of ovulation.			
ii. Intrauterine device.			
iii. Intrauterine hormone-releasing system.			
iv. Bilateral tubal occlusion.			
v. Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation:			
a. Oral			
b. Intravaginal			
c. Transdermal			
d. Injectable			
vi. Progestogen-only hormone contraception (oral or injectable) associated with inhibition of ovulation.			

Inclusion Criteria:			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
vii. Vasectomized partner viii. Sexual abstinence -this is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention. The reliability of sexual abstinence needs to be evaluated about the duration of the study and the preferred and usual lifestyle of the participant. ix. A combination of male condoms with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods) b. The following applies to all male participants in the study: i. Sexual abstinence- this is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention. The reliability of sexual abstinence must be evaluated for the study and the participant's preferred and usual lifestyle. ii. A combination of male condoms with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods). iii. Vasectomy			
8. Negative serum B-human chorionic gonadotropin test at screening (for all females) and negative urine pregnancy at randomization (Day 1) (females of childbearing potential) prior to administration of investigational product.	☐	☐	☐

Exclusion Criteria

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
1. History of clinically significant medical conditions or any other reason that in the opinion of the PI would interfere with subject's participation in this study	☐	☐	☐
2. History of clinically significant drug or alcohol abuse per the PI's opinion within the last 6 months.	☐	☐	☐
3. Pregnant or lactating women or women currently undergoing infertility treatments or women who intend to become pregnant during the time of study or for 6 weeks after last dose.	☐	☐	☐
4. Any known history of malignancy within 5 years other than completely treated non-metastatic basal cell carcinomas or squamous cell carcinomas of the skin or localized carcinoma in situ of the cervix.	☐	☐	☐
5. Any known history of a rheumatologic, autoimmune or cutaneous disease other than RA (except secondary Sjögren's syndrome), or psoriatic arthritis that could confound the assessments.	☐	☐	☐
6. Significant systemic involvement secondary to RA/PsA (active vasculitis, pulmonary fibrosis, or Felty's syndrome).	☐	☐	☐
7. Currently have non-plaque forms of psoriasis eg erythrodermic, guttate or pustular with the exception of nail psoriasis which is allowed.	☐	☐	☐
8. Receipt of an investigational therapy less than 3 months or 5 drug-elimination half-lives (whichever is longer) prior to first administration of study treatment and during the study	☐	☐	☐

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
9. Receipt of any of the following excluded therapies: Any cell depleting therapy, anti-CD4, anti-CD5, anti-CD3 other than anti-CD20 such as rituximab, ocrelizumab, and ofatumumab. Patients who have received rituximab or other selective B lymphocyte depleting agents (including experimental agents) are eligible if they have not received such therapy for at least 1 year prior to study baseline Have received prior tsDMARDs including but not limited to inhibitors of Janus kinase (JAK), Bruton tyrosine kinase, or tyrosine kinase 2, including baricitinib, tofacitinib, upadacitinib, filgotinib, ibrutinib, fenebrutinib, or apremilast in past month prior to screening or 5 drug elimination half-lives (whichever is longer) and throughout the study. Have received prior immunomodulatory bDMARDs including, but not limited to ustekinumab, secukinumab, abatacept, belimumab, anifrolumab within 4 weeks or 5 drug elimination half-lives whichever is longer and throughout the study. Receipt of any other DMARDs (not allowed per inclusion criterion 5) within less than 5 half-lives, prior to screening visit and throughout the study.	☐	☐	☐
10. Lack of response to ≥ 1 therapeutic agent targeting tumor necrosis factor or IL-6, or lack of response to > 2 bDMARDs (regardless of whether targeting different MOA or not).	☐	☐	☐
11. Use of psoriasis treatments: a. Oral or topical retinoids 2 weeks prior to Day 1 and throughout the study b. Topical treatments (steroids, or JAK inhibitors) within 2 weeks prior to Day 1 and throughout the study c. PUVA or UVB phototherapy within 4 weeks prior to Day 1 and throughout the study.	☐	☐	☐
12. No high potency opioid analgesics 2 weeks prior to baseline and during study. Analgesic dose must remain stable throughout from screening through completion of	☐	☐	☐

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
the study.			
13. Subject has clinical or laboratory evidence of active or latent TB infection at screening as assessed by QuantiFERON-TB-Gold or a purified protein derivative skin test or equivalent (or both if required per local guidelines) and chest X-ray. Chest X-rays taken within 2 months prior to screening may be used instead of during screening if there is documentation showing no evidence of infection or malignancy as read by qualified physician.	☐	☐	☐
14. Any active or recurrent infection within the past 4 weeks prior to screening requiring IV or oral antibiotics.	☐	☐	☐
15. Laboratory values of the following at the Screening Visit: Hemoglobin < 9 g/dL for males and < 8.5 g/dL for females WBC <3.5X10 ⁹ /L Absolute neutrophil count (ANC) < 1500 cells/ μ L , (or < 1200 cells/ μ L for participants of African descent who are black) Aspartate aminotransferase or alanine aminotransferase > 2.0 x the upper limit of normal (ULN) or bilirubin >= ULN; Bilirubin >ULN Platelets < 100,000 cells/[mm ³] (10 ⁹ /L); Clinically significant abnormal screening laboratory results as evaluated by the Investigator	☐	☐	☐
16. Acutely worsened renal function within past 3 months prior to screening or estimated GFR by CDK-EPI creatinine equation with adjustment for body surface area <60ml/min.	☐	☐	☐
17. Participants with a history of active or latent TB will be excluded from the study, unless documentation of complete TB treatment, consistent with local country	☐	☐	☐

Exclusion Criteria			
To be eligible for participation in the study, subjects must meet ALL of the following criteria	Yes	No	N/A
guidelines, can be provided.			
18. Subject has any clinically significant finding on 12-lead ECG at screening or admission. NOTE: QTc(F) interval of >450 msec in male participants or >470 msec in female participants will be the basis for exclusion from the study. ECG may be repeated once for confirmatory purposes if initial values obtained exceed the limits specified.	☐	☐	☐
19. Subject with positive results for HBsAg (hepatitis B surface antigens) and/or HBcAb (Hepatitis B core antibodies) and/or HCV Ab (hepatitis C antibodies) confirmed by HCV RNA, and/or HIV Ab (human immunodeficiency virus antibodies).	☐	☐	☐
20. Blood loss of >250 mL or donated blood within 56 days or donated plasma within 7 days of screening.	☐	☐	☐
21. Recent vaccination with live attenuated vaccines such as influenza, MMR, Herpes zoster, varicella, yellow fever, Rotavirus vaccine, etc., or inactivated vaccines such as Hepatitis A, rabies vaccine, etc. 30 days prior to screening visit	☐	☐	☐
22. History of infection 1) requiring hospitalization or parenteral antimicrobial therapy within 3 months prior to Day 1 or 2) treated with oral antimicrobial therapy within 2 weeks prior to Day 1.	☐	☐	☐
23. Subject is investigative site personnel, sponsor personnel, or a member of their immediate families (spouse, parent, child or sibling whether biological or legally adopted).	☐	☐	☐

Was body weight measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body weight measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

D

D

M

M

M

Y

Y

Y

Y

Weight | WEIGHT

Enter Weight

Weight Unit | WEIGHTU

Enter Custom Unit

Body Mass Index | BMI

BMI

BMI Unit | BMIU

Enter Custom Unit



Was Alcohol test performed? | AYN

- ☐ Yes
- ☐ No

Alcohol Sample Collection date | LBDAT1

Day | LBDAT1D

Month | LBDAT1M

Year | LBDAT1Y

D

D

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Y

Y

Y

Y

Alcohol test result | ACLO

- ☐ Positive
- ☐ Negative

Was the drug screening test performed? | DYN

- ☐ Yes
- ☐ No

Drug Sample Collection date | LBDAT2

Day | LBDAT2D

Month | LBDAT2M

Year | LBDAT2Y

D

D

M

M

M

Y

Y

Y

Y

Drug screening test result | DRUG

- ☐ Positive
- ☐ Negative

Was physical examination performed? | PEYN

- ☐ Yes
- ☐ No

Physical Examination Date | PEDAT

Day | PEDATD

Month | PEDATM

Year | PEDATY

D

D

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Y

Y

Physical Examination Time | PETIM

Hour | PETIMH

Minute | PETIMM

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M

Physical Examination Tests

Examination Test or Examination Name	Remark
General Appearance	Remark
Skin/ dermatological	Remark
Head, Ears, Eyes, Nose, and Throat Examination	Remark
Neck/ Thyroid	Remark
Lymphatic	Remark
Cardiovascular	Remark
Respiratory	Remark
Abdomen	Remark
Genitourinary	Remark
Nervous System	Remark

Examination Test or Examination Name	Remark
Musculoskeletal	Remark
Gastrointestinal	Remark
Extremities	Remark
Psychiatric disorders	Remark

Comment | PECOM

Enter comment if any

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Anti-CCP antibodies test assessed? | ACCPYN

- ☐ Yes
☐ No

Reason for not done | LBREASND

Enter Reason for not done

Sample Collected Date | COLLDAT

Day | COLLDATD Month | COLLDATM Year | COLLDATY

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Anti-CCP Level | ANTCCPP

Enter Anti-CCP Level

Unit | ANTCPPU

Enter Custom Unit

Reference Range | LBNRIND

- ☐ Normal
☐ Abnormal, clinically not significant
☐ Abnormal, clinically significant

Rheumatoid Factor | RFACTOR

- ☐ Positive
☐ Negative

Was Urine Pregnancy Test sample collected? | PREGYN

- ☐ Yes
- ☐ No

LBREASND | Reason Test Not Done

Enter Reason Test Not Done

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMY

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Urine Beta HCG | LBTEST

- ☐ Positive
- ☐ Negative
- ☐ Valid Result Not Obtained

Was the Specimen sample collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

D

D

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M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Urine Analysis Tests

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
pH	☐	☐	☐	☐	Remark
Specific gravity	☐	☐	☐	☐	Remark
Urine Micro - WBC	☐	☐	☐	☐	Remark
Urine Micro - RBC	☐	☐	☐	☐	Remark
Urine Micro - Cast	☐	☐	☐	☐	Remark
Urine Micro - Crystals	☐	☐	☐	☐	Remark
Urine Micro - Bacteria	☐	☐	☐	☐	Remark
Urine Micro - Yeast	☐	☐	☐	☐	Remark
Urine Micro - Parasites	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Protein	☐	☐	☐	☐	Remark
Glucose	☐	☐	☐	☐	Remark
Blood	☐	☐	☐	☐	Remark
Nitrite	☐	☐	☐	☐	Remark
Leucocytes	☐	☐	☐	☐	Remark
Ketones	☐	☐	☐	☐	Remark
Bilirubin	☐	☐	☐	☐	Remark
Color/appearance	☐	☐	☐	☐	Remark
Urobilinogen	☐	☐	☐	☐	Remark

Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD

Month | EGDATM

Year | EGDATY

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Y

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Y

Y

ECG Time | EGTIM

Hour | EGTIMH

Minute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation



Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOR

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD | Day

QSDATM | Month

QSDATY | Year

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Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐					
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	



Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0

Was HAQ - Disability Index assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Y

Y

Health Assessment Questionnaire-Disability Index score

In this section we are interested in learning how your illness affects your ability to function in daily life.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
- Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
- Stand up from a straight chair?	☐	☐	☐	☐
- Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
- Cut your meat?	☐	☐	☐	☐

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
- Lift a full cup or glass to your mouth?	☐	☐	☐	☐
- Open a new milk carton?	☐	☐	☐	☐
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Dressing and Grooming
- ☐ Arising
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Eating
- ☐ Walking

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
HYGIENE				
Are you able to:				

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
- Wash and dry your body?	☐	☐	☐	☐
- Take a tub bath?	☐	☐	☐	☐
- Get on and off the toilet?	☐	☐	☐	☐
REACH				
Are you able to:				
- Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
- Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
- Open car doors?	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
- Run errands and shop?	☐	☐	☐	☐
- Get in and out of a car?	☐	☐	☐	☐
- Do chores such as vacuuming or yardwork?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Raised toilet seat
- ☐ Bathtub seat
- ☐ Jar opener (for jars previously opened)
- ☐ Bathtub bar
- ☐ Long-handled appliances for reach
- ☐ Long-handled appliances in bathroom

☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

☐ Hygiene

☐ Reach

☐ Gripping and opening things

☐ Errands and chores



Was Patient's Arthritis Pain Assessed? | QAYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Pain Intensity





Was Patient Global Assessment of Disease Activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Disease Activity Score





Was Physician Global Assessment of disease activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Y

Disease Activity Score



Was Psoriasis Area and Severity Index assessed? | PASIYN

- ☐ Yes
☐ No
☐ NA

Reason for not done? | PASIREAND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Y

Assessment time | PASITIM

Hour | PASITIMH

Minute | PASITIMM

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Psoriasis Area and Severity Index

	Head
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Trunk
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Legs
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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M

Year | LBDATY

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Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATDMonth | EXDATMYear | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMHMinute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes

☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed valume



Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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Y

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Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

☐ Yes

☐ No

If No, mention the reason | REASND

Enter reason



PD whole Blood Sample collected ? | PDYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD Month | PDDATM Year | PDDATY

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PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH Minute | PDTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Other Specify

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

ECG Time (Triplicate Reading 1) | EGTIM1

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 1)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 1

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 2) | EGTIM2

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 2)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 2

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 3) | EGTIM3

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 3)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit ▾	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit ▾	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit ▾	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit ▾	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit ▾	☐	☐	☐	☐	Remark

ECG Interpretation 3

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOM

Enter Comment



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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M

Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any



Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

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Y

ECG Time (Triplicate Reading 1) | EGTIM1

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 1)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 1

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 2) | EGTIM2

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 2)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 2

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 3) | EGTIM3

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 3)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation 3

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOM

Enter Comment

Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

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Y

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Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

☐ Yes

☐ No

If No, mention the reason | REASND

Enter reason





Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

☐ Yes

☐ No

If No, mention the reason | REASND

Enter reason





Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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D

Month | LBDATM

M

M

M

Year | LBDATY

Y

Y

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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M

High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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ECG Time (Triplicate Reading 1) | EGTIM1

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 1)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 1

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 2) | EGTIM2

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 2)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 2

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 3) | EGTIM3

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 3)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation 3

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOM

Enter Comment

Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Y

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Y

Y

Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

- ☐ Yes
☐ No

If No, mention the reason | REASND

Enter reason



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Y

Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

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M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment



Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATDMonth | EXDATMYear | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMHMinute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes

☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed volume



Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD Month | PCDATM Year | PCDATY

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PK Blood Sample collection time | PCTIM

Hour | PCTIMH Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Dosing ? | DOSEYN

- ☐ Yes
- ☐ No

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

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M

M

Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Y

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Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

M

M

M

Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was Alcohol and Drug test performed? | ADYN

- ☐ Yes
☐ No

Reason Test Not Done | LBREASND

Enter Reason Test Not Done

Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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3,4-Methylenedioxymethamphetamine | MDMA

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Amphetamines | AMPHET

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Cannabinoids | THC

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Cocaine benzoylecgonine ecgonine | COCAINE

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Methadone | METHDN

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Opiate | OPIATE

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Oxycodone | OXYCON

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Phencyclidine | PCP

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Alcohol | ALCO

- ☐ Positive
☐ Negative

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

D

D

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Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes



☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed valume

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

PD whole Blood Sample collected ? | PDYN

- ☐ Yes
☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD Month | PDDATM Year | PDDATY

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Y

Y

PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH Minute | PDTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
☐ Schedule conflict
☐ Concurrent study activity
☐ Other Specify

Other Specify | PCREADEO

Other Specify

Dosing ? | DOSEYN

- ☐ Yes
☐ No

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD Month | EXDATM Year | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMH Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD Month | EXDATM Year | EXDATY

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D

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Y

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Dose Administration Time | EXTIM

Hour | EXTIMH Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was body weight measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body weight measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

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Y

Weight | WEIGHT

Enter Weight

Weight Unit | WEIGHTU

Enter Custom Unit

Body Mass Index | BMI

BMI

BMI Unit | BMIU

Enter Custom Unit

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Anti-CCP antibodies test assessed? | ACCPYN

- ☐ Yes
- ☐ No

Reason for not done | LBREASND

Enter Reason for not done

Sample Collected Date | COLLDAT

Day | COLLDATD

Month | COLLDATM

Year | COLLDATY

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Anti-CCP Level | ANTCCP

Enter Anti-CCP Level

Unit | ANTCCPU

Enter Custom Unit

Reference Range | LBNRIND

- ☐ Normal
- ☐ Abnormal, clinically not significant
- ☐ Abnormal, clinically significant

Rheumatoid Factor | RFACTOR

- ☐ Positive
- ☐ Negative

Was Urine Pregnancy Test sample collected? | PREGYN

- ☐ Yes
- ☐ No

LBREASND | Reason Test Not Done

Enter Reason Test Not Done

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMY

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Urine Beta HCG | LBTEST

- ☐ Positive
- ☐ Negative
- ☐ Valid Result Not Obtained

Was the Specimen sample collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Urine Analysis Tests

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
pH	☐	☐	☐	☐	Remark
Specific gravity	☐	☐	☐	☐	Remark
Urine Micro - WBC	☐	☐	☐	☐	Remark
Urine Micro - RBC	☐	☐	☐	☐	Remark
Urine Micro - Cast	☐	☐	☐	☐	Remark
Urine Micro - Crystals	☐	☐	☐	☐	Remark
Urine Micro - Bacteria	☐	☐	☐	☐	Remark
Urine Micro - Yeast	☐	☐	☐	☐	Remark
Urine Micro - Parasites	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Protein	☐	☐	☐	☐	Remark
Glucose	☐	☐	☐	☐	Remark
Blood	☐	☐	☐	☐	Remark
Nitrite	☐	☐	☐	☐	Remark
Leucocytes	☐	☐	☐	☐	Remark
Ketones	☐	☐	☐	☐	Remark
Bilirubin	☐	☐	☐	☐	Remark
Color/appearance	☐	☐	☐	☐	Remark
Urobilinogen	☐	☐	☐	☐	Remark

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATDMonth | EXDATMYear | EXDATY

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMHMinute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes

☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed volume



Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

PD whole Blood Sample collected ? | PDYN

- ☐ Yes
☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD

Month | PDDATM

Year | PDDATY

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Y

Y

Y

Y

PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH

Minute | PDTIMM

H

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M

Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
☐ Schedule conflict
☐ Concurrent study activity
☐ Other Specify

Other Specify | PCREADEO

Other Specify

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

Y

Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

H

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOR

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
- ☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD | Day

QSDATM | Month

QSDATY | Year

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Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right								
Tender			Swelling					Tender			Swelling					
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA		
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐						
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	☐	



Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0

Was HAQ - Disability Index assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Health Assessment Questionnaire-Disability Index score

In this section we are interested in learning how your illness affects your ability to function in daily life.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
- Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
- Stand up from a straight chair?	☐	☐	☐	☐
- Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
- Cut your meat?	☐	☐	☐	☐

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
- Lift a full cup or glass to your mouth?	☐	☐	☐	☐
- Open a new milk carton?	☐	☐	☐	☐
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Dressing and Grooming
- ☐ Arising
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Eating
- ☐ Walking

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
HYGIENE				
Are you able to:				

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
- Wash and dry your body?	☐	☐	☐	☐
- Take a tub bath?	☐	☐	☐	☐
- Get on and off the toilet?	☐	☐	☐	☐
REACH				
Are you able to:				
- Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
- Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
- Open car doors?	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
- Run errands and shop?	☐	☐	☐	☐
- Get in and out of a car?	☐	☐	☐	☐
- Do chores such as vacuuming or yardwork?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Raised toilet seat
- ☐ Bathtub seat
- ☐ Jar opener (for jars previously opened)
- ☐ Bathtub bar
- ☐ Long-handled appliances for reach
- ☐ Long-handled appliances in bathroom

☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

☐ Hygiene

☐ Reach

☐ Gripping and opening things

☐ Errands and chores



Was Patient's Arthritis Pain Assessed? | QAYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day QSDATD		Month QSDATM			Year QSDATY			
D	D	M	M	M	Y	Y	Y	Y

Pain Intensity





Was Physician Global Assessment of disease activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Disease Activity Score



Was Psoriasis Area and Severity Index assessed? | PASIYN

- ☐ Yes
☐ No
☐ NA

Reason for not done? | PASIREAND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Assessment time | PASITIM

Hour | PASITIMH

Minute | PASITIMM

H

H

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M

Psoriasis Area and Severity Index

	Head
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Trunk
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Legs
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Dosing ? | DOSEYN

- ☐ Yes
☐ No

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

H

H

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M

Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

M

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M

Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

H

H

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

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M

Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

M

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

H

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

M

M

M

Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

H

H

M

M

Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

D

D

M

M

M

Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

H

H

M

M

Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Y

Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

H

H

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Study Dose Administered? | EXYN

- ☐ Yes
☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATDMonth | EXDATMYear | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMHMinute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes



☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed valume



Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

PD whole Blood Sample collected ? | PDYN

- ☐ Yes
☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD

Month | PDDATM

Year | PDDATY

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Y

Y

Y

Y

PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH Minute | PDTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
☐ Schedule conflict
☐ Concurrent study activity
☐ Other Specify

Other Specify | PCREADEO

Other Specify

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATDMonth | EGDATMYear | EGDATY

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Y

ECG Time | EGTIM

Hour | EGTIMHMinute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation



Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOM

Enter Comment

Dosing ? | DOSEYN

☐ Yes

☐ No

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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D

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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M

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

Enter If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATD

Month | EXDATM

Year | EXDATY

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Y

Y

Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMH

Minute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was Alcohol and Drug test performed? | ADYN

- ☐ Yes
☐ No

Reason Test Not Done | LBREASND

Enter Reason Test Not Done

Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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3,4-Methylenedioxymethamphetamine | MDMA

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Amphetamines | AMPHET

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Cannabinoids | THC

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Cocaine benzoylecgonine ecgonine | COCAINE

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Methadone | METHDN

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Opiate | OPIATE

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Oxycodone | OXYCON

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Phencyclidine | PCP

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Alcohol | ALCO

- ☐ Positive
☐ Negative

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAS

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATDMonth | EXDATMYear | EXDATY

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Y

Y

Dose Administration Time | EXTIM

Hour | EXTIMHMinute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes

☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed volume



Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

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Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

PD whole Blood Sample collected ? | PDYN

- ☐ Yes
☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD Month | PDDATM Year | PDDATY

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D

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M

Y

Y

Y

Y

PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH Minute | PDTIMM

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H

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
☐ Schedule conflict
☐ Concurrent study activity
☐ Other Specify

Other Specify | PCREADEO

Other Specify

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

Y

Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGC

Enter Comment



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Y

Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING
- ☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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M

Year | LBDATY

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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H

Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Study Dose Administered? | EXYN

- ☐ Yes
- ☐ No

If No, specify reason | EXREASND

If No, specify reason

Dose Administration Date | EXDAT

Day | EXDATDMonth | EXDATMYear | EXDATY

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Y

Dose Administration Time | EXTIM

Hour | EXTIMHMinute | EXTIMM

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Was a Subject fasting? | SFAST

- ☐ Yes
- ☐ No

Subject swallow the entire volume? | SVOLYN

- ☐ Yes
- ☐ No

Left Volume | LEFTVOL

Enter Left Volume

No reason | REASNNS

Enter reason for not swallow the entire volume

The Subject Swallowed the rinsed volume? | RINSVYN

- ☐ Yes

☐ No

Reason | REASON

Enter reason for not Subject Swallowed the rinsed volume



Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

☐ Yes

☐ No

If No, mention the reason | REASND

Enter reason



Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD

Month | EGDATM

Year | EGDATY

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Y

Y

Y

Y

ECG Time (Triplicate Reading 1) | EGTIM1

Hour | EGTIMH

Minute | EGTIMM

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ECG Tests (Triplicate Reading 1)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 1

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 2) | EGTIM2

Hour | EGTIMH Minute | EGTIMM

H

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ECG Tests (Triplicate Reading 2)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 2

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 3) | EGTIM3

Hour | EGTIMH Minute | EGTIMM

H

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ECG Tests (Triplicate Reading 3)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation 3

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOM

Enter Comment

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
D	D	M	M	M	Y	Y	Y	Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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D

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Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

D

D

M

M

M

Y

Y

Y

Y

Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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D

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Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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M

High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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ECG Time (Triplicate Reading 1) | EGTIM1

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 1)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 1

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 2) | EGTIM2

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 2)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 2

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 3) | EGTIM3

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 3)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation 3

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOM

Enter Comment



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

- ☐ Yes
☐ No

If No, mention the reason | REASND

Enter reason 

Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

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Y

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Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

- ☐ Yes
☐ No

If No, mention the reason | REASND

Enter reason 

Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	☐	☐	☐	☐	Remark
White Blood Cells	☐	☐	☐	☐	Remark
Hemoglobin	☐	☐	☐	☐	Remark
Hematocrit	☐	☐	☐	☐	Remark
Platelets	☐	☐	☐	☐	Remark
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	○	○	○	○	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Phosphorus	☐	☐	☐	☐	Remark
Low-density lipoprotein (LDL)	☐	☐	☐	☐	Remark
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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Year | LBDATY

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Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD

Month | EGDATM

Year | EGDATY

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Y

ECG Time (Triplicate Reading 1) | EGTIM1

Hour | EGTIMH

Minute | EGTIMM

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ECG Tests (Triplicate Reading 1)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 1

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 2) | EGTIM2

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 2)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation 2

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

ECG Time (Triplicate Reading 3) | EGTIM3

Hour | EGTIMH Minute | EGTIMM

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ECG Tests (Triplicate Reading 3)

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation 3

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | ECGOM

Enter Comment

Visit Date | VISITDAT

Day VISITDATD		Month VISITDATM			Year VISITDATY			
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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

D

D

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Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Did you assign one-third of the plasma sample collected for PK analysis to be used for PD analysis? | PDSYN

- ☐ Yes
☐ No

If No, mention the reason | REASND

Enter reason 



Visit Date | VISITDAT

Day | VISITDATD

Month | VISITDATM

Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was the blood sample collected? | PCYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD

Month | PCDATM

Year | PCDATY

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D

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M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH

Minute | PCTIMM

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Visit Date | VISITDAT

Day | VISITDATD Month | VISITDATM Year | VISITDATY

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Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was physical examination performed? | PEYN

- ☐ Yes
☐ No

Physical Examination Date | PEDAT

Day | PEDATD

Month | PEDATM

Year | PEDATY

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Physical Examination Time | PETIM

Hour | PETIMH

Minute | PETIMM

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Physical Examination Tests

Examination Test or Examination Name	Remark
General Appearance	Remark
Skin/ dermatological	Remark
Head, Ears, Eyes, Nose, and Throat Examination	Remark
Neck/ Thyroid	Remark
Lymphatic	Remark
Cardiovascular	Remark
Respiratory	Remark
Abdomen	Remark
Genitourinary	Remark
Nervous System	Remark
Musculoskeletal	Remark

Examination Test or Examination Name	Remark
Gastrointestinal	Remark
Extremities	Remark
Psychiatric disorders	Remark

Comment | PECOM

Enter comment if any

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATDMonth | VSDATMYear | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMHMinute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
☐ SITTING



☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit



Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

H

H

M

M

Was the subject Fasting? | LBFAST

- ☐ Yes
☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	☐	☐	☐	☐	Remark
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark
Phosphorus	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

D

D

Month | LBDATM

M

M

M

Year | LBDATY

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

H

H

Minute | LBTIMM

M

M

High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	Result	Select Unit	Limit	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

H

H

M

M

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

☐ Yes

☐ No

☐ NA

Was Anti-CCP antibodies test assessed? | ACCPYN

- ☐ Yes
- ☐ No

Reason for not done | LBREASND

Enter Reason for not done

Sample Collected Date | COLLDAT

Day | COLLDATD

Month | COLLDATM

Year | COLLDATY

D

D

M

M

M

Y

Y

Y

Y

Anti-CCP Level | ANTCCP

Enter Anti-CCP Level

Unit | ANTCCPU

Enter Custom Unit

Reference Range | LBNRIND

- ☐ Normal
- ☐ Abnormal, clinically not significant
- ☐ Abnormal, clinically significant

Rheumatoid Factor | RFACTOR

- ☐ Positive
- ☐ Negative

Was Urine Pregnancy Test sample collected? | PREGYN

- ☐ Yes
- ☐ No

LBREASND | Reason Test Not Done

Enter Reason Test Not Done

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMY

H

H

M

M

Urine Beta HCG | LBTEST

- ☐ Positive
- ☐ Negative
- ☐ Valid Result Not Obtained

Was the Specimen sample collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

H

H

M

M

Urine Analysis Tests

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
pH	○	○	○	○	Remark
Specific gravity	○	○	○	○	Remark
Urine Micro - WBC	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Urine Micro - Crystals	☐	☐	☐	☐	Remark
Urine Micro - Bacteria	☐	☐	☐	☐	Remark
Urine Micro - Yeast	☐	☐	☐	☐	Remark
Urine Micro - Parasites	☐	☐	☐	☐	Remark
Protein	☐	☐	☐	☐	Remark
Glucose	☐	☐	☐	☐	Remark
Blood	☐	☐	☐	☐	Remark
Nitrite	☐	☐	☐	☐	Remark
Leucocytes	☐	☐	☐	☐	Remark
Ketones	☐	☐	☐	☐	Remark
Bilirubin	☐	☐	☐	☐	Remark
Color/appearance	☐	☐	☐	☐	Remark
Urobilinogen	☐	☐	☐	☐	Remark

Was the blood sample collected? | PCYN

- ☐ Yes
☐ No

Reasons for sample not collected | PCREASND

Enter reasons for sample not collected

PK Blood Sample collection Date | PCDAT

Day | PCDATD Month | PCDATM Year | PCDATY

D

D

M

M

M

Y

Y

Y

Y

PK Blood Sample collection time | PCTIM

Hour | PCTIMH Minute | PCTIMM

H

H

M

M

Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
☐ Schedule conflict
☐ Concurrent study activity
☐ Other Specify

Other Specify | PCREADEO

Enter Other Specify

Comment | COMMENT

Enter Comment if any

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

D

D

M

M

M

Y

Y

Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

H

H

M

M

ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOR

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
- ☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD | Day

QSDATM | Month

QSDATY | Year

D

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Y

Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right								
Tender			Swelling					Tender			Swelling					
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA		
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐						
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	☐	

Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0

Was HAQ - Disability Index assessed? | QSYN

- ☐ Yes
☐ No

Reason for not done | QSREASND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD Month | QSDATM Year | QSDATY

D

D

M

M

M

Y

Y

Y

Y

Health Assessment Questionnaire-Disability Index score

In this section we are interested in learning how your illness affects your ability to function in daily life.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
- Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
- Stand up from a straight chair?	☐	☐	☐	☐
- Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
- Cut your meat?	☐	☐	☐	☐
- Lift a full cup or glass to your mouth?	☐	☐	☐	☐
- Open a new milk carton?	☐	☐	☐	☐

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Dressing and Grooming
- ☐ Arising
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Eating
- ☐ Walking

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
HYGIENE				
Are you able to:				
- Wash and dry your body?	☐	☐	☐	☐
- Take a tub bath?	☐	☐	☐	☐
- Get on and off the toilet?	☐	☐	☐	☐
REACH				

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
Are you able to:				
- Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
- Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
- Open car doors?	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
- Run errands and shop?	☐	☐	☐	☐
- Get in and out of a car?	☐	☐	☐	☐
- Do chores such as vacuuming or yardwork?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Raised toilet seat
- ☐ Bathtub seat
- ☐ Jar opener (for jars previously opened)
- ☐ Bathtub bar
- ☐ Long-handled appliances for reach
- ☐ Long-handled appliances in bathroom
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Hygiene
- ☐ Reach
- ☐ Gripping and opening things
- ☐ Errands and chores

Was Patient's Arthritis Pain Assessed? | QAYN

- ☐ Yes
☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

D

D

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M

M

Y

Y

Y

Y

Pain Intensity



Was Patient Global Assessment of Disease Activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

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Y

Disease Activity Score



Was Physician Global Assessment of disease activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Disease Activity Score



Was Psoriasis Area and Severity Index assessed? | PASIYN

- ☐ Yes
☐ No
☐ NA

Reason for not done? | PASIREAND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

Assessment time | PASITIM

Hour | PASITIMH

Minute | PASITIMM

Psoriasis Area and Severity Index

	Head
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Trunk
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Legs
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Visit Date | VISITDAT

Day | VISITDATD Month | VISITDATM Year | VISITDATY

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Visit Date | VISITDAT

Day | VISITDATD Month | VISITDATM Year | VISITDATY

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Y

Y

Y

Y

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was Alcohol and Drug test performed? | ADYN

- ☐ Yes
☐ No

Reason Test Not Done | LBREASND

Enter Reason Test Not Done

Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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D

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M

Y

Y

Y

Y

Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMM

H

H

M

M

3,4-Methylenedioxymethamphetamine | MDMA

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Amphetamines | AMPHET

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Cannabinoids | THC

- ☐ Positive
☐ Negative
☐ Not Done

Reason for Not Done | REASND

Cocaine benzoylecgonine ecgonine | COCAINE

- ☐ Positive
- ☐ Negative
- ☐ Not Done

Reason for Not Done | REASND

Methadone | METHDN

- ☐ Positive
- ☐ Negative
- ☐ Not Done

Reason for Not Done | REASND

Opiate | OPIATE

- ☐ Positive
- ☐ Negative
- ☐ Not Done

Reason for Not Done | REASND

Oxycodone | OXYCON

- ☐ Positive
- ☐ Negative
- ☐ Not Done

Reason for Not Done | REASND

Phencyclidine | PCP

- ☐ Positive

☐ Negative

☐ Not Done

Reason for Not Done | REASND

Alcohol | ALCO

☐ Positive

☐ Negative

Were Vital Signs Performed? | VSPERF

- ☐ Yes
☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Y

Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit	☐	☐	☐	☐	Remark
Diastolic Blood Pressure	Result	Select Unit	☐	☐	☐	☐	Remark
Heart Rate	Result	Select Unit	☐	☐	☐	☐	Remark
Temperature	Result	Select Unit	☐	☐	☐	☐	Remark
Respiratory Rate	Result	Select Unit	☐	☐	☐	☐	Remark
Oxygen Saturation	Result	Select Unit	☐	☐	☐	☐	Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
☐ SITTING



☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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D

Month | LBDATM

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M

M

Year | LBDATY

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Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH

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H

Minute | LBTIMM

M

M

Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

D

D

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M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

H

H

M

M

Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

PD whole Blood Sample collected ? | PDYN

- ☐ Yes
☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD Month | PDDATM Year | PDDATY

D

D

M

M

M

Y

Y

Y

Y

PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH Minute | PDTIMM

H

H

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M

Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
☐ Schedule conflict
☐ Concurrent study activity
☐ Other Specify

Other Specify | PCREADEO

Other Specify

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

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Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOR

Enter Comment

Visit Date | VISITDAT

Day | VISITDATD Month | VISITDATM Year | VISITDATY

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Visit activity performed | VISITAYN

☐ Yes

☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was body weight measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body weight measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

D

D

M

M

M

Y

Y

Y

Y

Weight | WEIGHT

Enter Weight

Weight Unit | WEIGHTU

Enter Custom Unit

Body Mass Index | BMI

BMI

BMI Unit | BMIU

Enter Custom Unit

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD Month | VSDATM Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING

☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	☐	☐	☐	☐	Remark
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark
Phosphorus	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

D

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Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Anti-CCP antibodies test assessed? | ACCPYN

- ☐ Yes
- ☐ No

Reason for not done | LBREASND

Enter Reason for not done

Sample Collected Date | COLLDAT

Day | COLLDATD Month | COLLDATM Year | COLLDATY

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Anti-CCP Level | ANTCCP

Enter Anti-CCP Level

Unit | ANTCCPU

Enter Custom Unit

Reference Range | LBNRIND

- ☐ Normal
- ☐ Abnormal, clinically not significant
- ☐ Abnormal, clinically significant

Rheumatoid Factor | RFACTOR

- ☐ Positive
- ☐ Negative

PD whole Blood Sample collected ? | PDYN

- ☐ Yes
- ☐ No

Reasons for sample not collected | PCREASND

Enter Reasons for sample not collected

PD whole Blood Sample collection | PDDAT

Day | PDDATD Month | PDDATM Year | PDDATY

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Y

Y

Y

Y

PD whole Blood Sample collection time | PDTIM

Hour | PDTIMH Minute | PDTIMM

H

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Comment- If sample is delayed | PCREADL

- ☐ Difficulty in Phlebotomy
- ☐ Schedule conflict
- ☐ Concurrent study activity
- ☐ Other Specify

Other Specify | PCREADEO

Other Specify

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

Y

Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOR

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
- ☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD | Day

QSDATM | Month

QSDATY | Year

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Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right								
Tender			Swelling					Tender			Swelling					
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA		
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐						
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	☐	

Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0

Was HAQ - Disability Index assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD Month | QSDATM Year | QSDATY

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Y

Y

Y

Health Assessment Questionnaire-Disability Index score

In this section we are interested in learning how your illness affects your ability to function in daily life.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
- Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
- Stand up from a straight chair?	☐	☐	☐	☐
- Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
- Cut your meat?	☐	☐	☐	☐
- Lift a full cup or glass to your mouth?	☐	☐	☐	☐
- Open a new milk carton?	☐	☐	☐	☐

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Dressing and Grooming
- ☐ Arising
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Eating
- ☐ Walking

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
HYGIENE				
Are you able to:				
- Wash and dry your body?	☐	☐	☐	☐
- Take a tub bath?	☐	☐	☐	☐
- Get on and off the toilet?	☐	☐	☐	☐
REACH				

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
Are you able to:				
- Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
- Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
- Open car doors?	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
- Run errands and shop?	☐	☐	☐	☐
- Get in and out of a car?	☐	☐	☐	☐
- Do chores such as vacuuming or yardwork?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Raised toilet seat
- ☐ Bathtub seat
- ☐ Jar opener (for jars previously opened)
- ☐ Bathtub bar
- ☐ Long-handled appliances for reach
- ☐ Long-handled appliances in bathroom
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Hygiene
- ☐ Reach
- ☐ Gripping and opening things
- ☐ Errands and chores

Was Patient's Arthritis Pain Assessed? | QAYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Pain Intensity



Was Patient Global Assessment of Disease Activity performed? | QSYN

- ☐ Yes
☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Disease Activity Score



Was Physician Global Assessment of disease activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Y

Y

Disease Activity Score



Was Psoriasis Area and Severity Index assessed? | PASIYN

- ☐ Yes
☐ No
☐ NA

Reason for not done? | PASIREAND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD Month | QSDATM Year | QSDATY

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Y

Assessment time | PASITIM

Hour | PASITIMH Minute | PASITIMM

H

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Psoriasis Area and Severity Index

	Head
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Trunk
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Legs
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Visit Date | VISITDAT

Day | VISITDATD Month | VISITDATM Year | VISITDATY

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Visit activity performed | VISITAYN

- ☐ Yes
- ☐ No

If No: [Specify reason for not performed] | VISITANR

If No: [Specify reason for not performed]

Was body height measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body height measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

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Y

Height | HEIGHT

Enter Height

Height Unit | HEIGHTU

Enter Custom Unit

Was body weight measured? | VSYN

- ☐ Yes
- ☐ No

Reason for not done | VSREASN

Reason for not done

Date of body weight measurements | VSDAT

Day | VSDATD

Month | VSDATM

Year | VSDATY

D

D

M

M

M

Y

Y

Y

Y

Weight | WEIGHT

Enter Weight

Weight Unit | WEIGHTU

Enter Custom Unit

Body Mass Index | BMI

BMI

BMI Unit | BMIU

Enter Custom Unit

Was physical examination performed? | PEYN

- ☐ Yes
☐ No

Physical Examination Date | PEDAT

Day | PEDATD

Month | PEDATM

Year | PEDATY

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Y

Physical Examination Time | PETIM

Hour | PETIMH

Minute | PETIMM

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Physical Examination Tests

Examination Test or Examination Name	Remark
General Appearance	Remark
Skin/ dermatological	Remark
Head, Ears, Eyes, Nose, and Throat Examination	Remark
Neck/ Thyroid	Remark
Lymphatic	Remark
Cardiovascular	Remark
Respiratory	Remark
Abdomen	Remark
Genitourinary	Remark
Nervous System	Remark
Musculoskeletal	Remark

Examination Test or Examination Name	Remark
Gastrointestinal	Remark
Extremities	Remark
Psychiatric disorders	Remark

Comment | PECOM

Enter comment if any

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD

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Month | VSDATM

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Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH

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Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING

☐ SUPINE

Comment | VSCOM

Enter Comment



Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD

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Month | LBDATM

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M

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Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

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H

Minute | LBTIMM

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M

Was the subject Fasting? | LBFAST

- ☐ Yes
- ☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	☐	☐	☐	☐	Remark
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark
Phosphorus	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

D

D

M

M

M

Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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High-Sensitivity CRP (hs-CRP)

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
High-Sensitivity CRP (hs-CRP)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-Sensitivity CRP (hs-CRP)	☐	☐	☐	☐	Remark

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Y

Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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M

Erythrocyte sedimentation rate | ESR

Enter Erythrocyte sedimentation rate

Erythrocyte sedimentation rate unit | ESRU

Enter Custom Unit

Was the Specimen collected? | LBYN

- ☐ Yes
- ☐ No
- ☐ NA

Was Anti-CCP antibodies test assessed? | ACCPYN

- ☐ Yes
- ☐ No

Reason for not done | LBREASND

Enter Reason for not done

Sample Collected Date | COLLDAT

Day | COLLDATD

Month | COLLDATM

Year | COLLDATY

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D

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Y

Y

Y

Y

Anti-CCP Level | ANTCCP

Enter Anti-CCP Level

Unit | ANTCCPU

Enter Custom Unit

Reference Range | LBNRIND

- ☐ Normal
- ☐ Abnormal, clinically not significant
- ☐ Abnormal, clinically significant

Rheumatoid Factor | RFACTOR

- ☐ Positive
- ☐ Negative

Was Urine Pregnancy Test sample collected? | PREGYN

- ☐ Yes
- ☐ No

LBREASND | Reason Test Not Done

Enter Reason Test Not Done

Specimen Collection Date | LBDAT

Day | LBDATD

Month | LBDATM

Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH

Minute | LBTIMY

H

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Urine Beta HCG | LBTEST

- ☐ Positive
- ☐ Negative
- ☐ Valid Result Not Obtained

Was the Specimen sample collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Y

Y

Y

Y

Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

H

H

M

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Urine Analysis Tests

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Blood	=	▼	Result	Select Unit ▼	Limit	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
pH	○	○	○	○	Remark
Specific gravity	○	○	○	○	Remark
Urine Micro - WBC	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Urine Micro - Crystals	☐	☐	☐	☐	Remark
Urine Micro - Bacteria	☐	☐	☐	☐	Remark
Urine Micro - Yeast	☐	☐	☐	☐	Remark
Urine Micro - Parasites	☐	☐	☐	☐	Remark
Protein	☐	☐	☐	☐	Remark
Glucose	☐	☐	☐	☐	Remark
Blood	☐	☐	☐	☐	Remark
Nitrite	☐	☐	☐	☐	Remark
Leucocytes	☐	☐	☐	☐	Remark
Ketones	☐	☐	☐	☐	Remark
Bilirubin	☐	☐	☐	☐	Remark
Color/appearance	☐	☐	☐	☐	Remark
Urobilinogen	☐	☐	☐	☐	Remark

Were ECG examination assessed? | EGYN

- ☐ Yes
☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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Y

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Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit					Remark
RR Interval	Result	Select Unit					Remark
QRS Interval	Result	Select Unit					Remark
QT Interval	Result	Select Unit					Remark
QTcF	Result	Select Unit					Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | EGCOR

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
- ☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD | Day

QSDATM | Month

QSDATY | Year

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Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right								
Tender			Swelling					Tender			Swelling					
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA		
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐						
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	☐	

Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0

Was HAQ - Disability Index assessed? | QSYN

- ☐ Yes
☐ No

Reason for not done | QSREASND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD Month | QSDATM Year | QSDATY

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Y

Y

Y

Y

Health Assessment Questionnaire-Disability Index score

In this section we are interested in learning how your illness affects your ability to function in daily life.

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
- Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
- Stand up from a straight chair?	☐	☐	☐	☐
- Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
- Cut your meat?	☐	☐	☐	☐
- Lift a full cup or glass to your mouth?	☐	☐	☐	☐
- Open a new milk carton?	☐	☐	☐	☐

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Dressing and Grooming
- ☐ Arising
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Eating
- ☐ Walking

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
HYGIENE				
Are you able to:				
- Wash and dry your body?	☐	☐	☐	☐
- Take a tub bath?	☐	☐	☐	☐
- Get on and off the toilet?	☐	☐	☐	☐
REACH				

	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
Are you able to:				
- Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
- Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
- Open car doors?	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
- Run errands and shop?	☐	☐	☐	☐
- Get in and out of a car?	☐	☐	☐	☐
- Do chores such as vacuuming or yardwork?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of these activities:

- ☐ Raised toilet seat
- ☐ Bathtub seat
- ☐ Jar opener (for jars previously opened)
- ☐ Bathtub bar
- ☐ Long-handled appliances for reach
- ☐ Long-handled appliances in bathroom
- ☐ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ☐ Hygiene
- ☐ Reach
- ☐ Gripping and opening things
- ☐ Errands and chores

Was Patient's Arthritis Pain Assessed? | QAYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Pain Intensity



Was Patient Global Assessment of Disease Activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Disease Activity Score



Was Physician Global Assessment of disease activity performed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done | QSREASND

Specify Reason for not done

Assessment Date | QSDAT

Day | QSDATD

Month | QSDATM

Year | QSDATY

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Y

Disease Activity Score



Was Psoriasis Area and Severity Index assessed? | PASIYN

- ☐ Yes
☐ No
☐ NA

Reason for not done? | PASIREAND

Reason for not done

Assessment Date | QSDAT

Day | QSDATD Month | QSDATM Year | QSDATY

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Y

Assessment time | PASITIM

Hour | PASITIMH Minute | PASITIMM

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Psoriasis Area and Severity Index

	Head
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Arms
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Trunk
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

	Legs
Percentage Affected Area	☐ 0% ☐ <10% ☐ 10-29% ☐ 30-49% ☐ 50-69% ☐ 70-89% ☐ 90-100%
Erythema (redness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Induration (thickness)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Desquamation (scaling)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

Unscheduled Visit? | UNSYN

☐ Yes

☐ No

Were Vital Signs Performed? | VSPERF

- ☐ Yes
- ☐ No

If No, Mention the reason | VSREASND

If No, Mention the reason

Vital Signs Date | VSDAT

Day | VSDATD

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Month | VSDATM

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Year | VSDATY

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Vital Signs Time | VSTIM

Hour | VSTIMH

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Minute | VSTIMM

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Vital Signs

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
Systolic Blood Pressure	Result	Select Unit					Remark
Diastolic Blood Pressure	Result	Select Unit					Remark
Heart Rate	Result	Select Unit					Remark
Temperature	Result	Select Unit					Remark
Respiratory Rate	Result	Select Unit					Remark
Oxygen Saturation	Result	Select Unit					Remark

Vital Signs Position of Subject | VSPOS

- ☐ STANDING
- ☐ SITTING



☐ SUPINE

Comment | VSCOM

Enter Comment

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Hematology Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Red Blood Cells	=	▼	Result	Select Unit ▼	Limit
White Blood Cells	=	▼	Result	Select Unit ▼	Limit
Hemoglobin	=	▼	Result	Select Unit ▼	Limit
Hematocrit	=	▼	Result	Select Unit ▼	Limit
Platelets	=	▼	Result	Select Unit ▼	Limit
Prothrombin Time	=	▼	Result	Select Unit ▼	Limit
International Normalized Ratio	=	▼	Result	Select Unit ▼	Limit
Activated Partial Thromboplastin Time (aPTT)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Percent)	=	▼	Result	Select Unit ▼	Limit
Neutrophils (Absolute)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Percent)	=	▼	Result	Select Unit ▼	Limit
Lymphocyte (Absolute)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Percent)	=	▼	Result	Select Unit ▼	Limit
Monocytes (Absolute)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Eosinophil (Absolute)	=	▼	Result	Select Unit ▼	Limit
Basophil (Percent)	=	▼	Result	Select Unit ▼	Limit
Basophil (Absolute)	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Red Blood Cells	○	○	○	○	Remark
White Blood Cells	○	○	○	○	Remark
Hemoglobin	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Prothrombin Time	☐	☐	☐	☐	Remark
International Normalized Ratio	☐	☐	☐	☐	Remark
Activated Partial Thromboplastin Time (aPTT)	☐	☐	☐	☐	Remark
Neutrophils (Percent)	☐	☐	☐	☐	Remark
Neutrophils (Absolute)	☐	☐	☐	☐	Remark
Lymphocyte (Percent)	☐	☐	☐	☐	Remark
Lymphocyte (Absolute)	☐	☐	☐	☐	Remark
Monocytes (Percent)	☐	☐	☐	☐	Remark
Monocytes (Absolute)	☐	☐	☐	☐	Remark
Eosinophil (Percent)	☐	☐	☐	☐	Remark
Eosinophil (Absolute)	☐	☐	☐	☐	Remark
Basophil (Percent)	☐	☐	☐	☐	Remark
Basophil (Absolute)	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATDMonth | LBDATMYear | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMHMinute | LBTIMM

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Was the subject Fasting? | LBFAST

- ☐ Yes
☐ No

Serum Chemistry Test

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
Alanine aminotransferase	=	▼	Result	Select Unit ▼	Limit
Albumin	=	▼	Result	Select Unit ▼	Limit
Alkaline phosphatase	=	▼	Result	Select Unit ▼	Limit
Aspartate aminotransferase	=	▼	Result	Select Unit ▼	Limit
Total bilirubin	=	▼	Result	Select Unit ▼	Limit
Direct bilirubin	=	▼	Result	Select Unit ▼	Limit
Total protein	=	▼	Result	Select Unit ▼	Limit
Creatinine	=	▼	Result	Select Unit ▼	Limit
Blood urea nitrogen	=	▼	Result	Select Unit ▼	Limit
Creatine kinase	=	▼	Result	Select Unit ▼	Limit
Gamma-glutamyl transferase (GGT)	=	▼	Result	Select Unit ▼	Limit
Potassium	=	▼	Result	Select Unit ▼	Limit
Sodium	=	▼	Result	Select Unit ▼	Limit
Fasting Glucose	=	▼	Result	Select Unit ▼	Limit
Bicarbonate	=	▼	Result	Select Unit ▼	Limit
Calcium	=	▼	Result	Select Unit ▼	Limit
Amylase	=	▼	Result	Select Unit ▼	Limit
Lipase	=	▼	Result	Select Unit ▼	Limit
Magnesium	=	▼	Result	Select Unit ▼	Limit
Phosphorus	=	▼	Result	Select Unit ▼	Limit
Low-density lipoprotein (LDL)	=	▼	Result	Select Unit ▼	Limit
High-density lipoprotein (HDL)	=	▼	Result	Select Unit ▼	Limit
Total cholesterol	=	▼	Result	Select Unit ▼	Limit
Triglycerides	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Alanine aminotransferase	☐	☐	☐	☐	Remark
Albumin	☐	☐	☐	☐	Remark
Alkaline phosphatase	☐	☐	☐	☐	Remark
Aspartate aminotransferase	☐	☐	☐	☐	Remark
Total bilirubin	☐	☐	☐	☐	Remark
Direct bilirubin	☐	☐	☐	☐	Remark
Total protein	☐	☐	☐	☐	Remark
Creatinine	☐	☐	☐	☐	Remark
Blood urea nitrogen	☐	☐	☐	☐	Remark
Creatine kinase	☐	☐	☐	☐	Remark
Gamma-glutamyl transferase (GGT)	☐	☐	☐	☐	Remark
Potassium	☐	☐	☐	☐	Remark
Sodium	☐	☐	☐	☐	Remark
Fasting Glucose	☐	☐	☐	☐	Remark
Bicarbonate	☐	☐	☐	☐	Remark
Calcium	☐	☐	☐	☐	Remark
Amylase	☐	☐	☐	☐	Remark
Lipase	☐	☐	☐	☐	Remark
Magnesium	☐	☐	☐	☐	Remark
Phosphorus	☐	☐	☐	☐	Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
High-density lipoprotein (HDL)	☐	☐	☐	☐	Remark
Total cholesterol	☐	☐	☐	☐	Remark
Triglycerides	☐	☐	☐	☐	Remark

Comment | LBCOM

Enter Comment if any

Was the Specimen sample collected? | LBYN

- ☐ Yes
☐ No

If No, specify reason | LBREASND

If No, specify reason

Specimen Collection Date | LBDAT

Day | LBDATD Month | LBDATM Year | LBDATY

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Specimen Collection Time | LBTIM

Hour | LBTIMH Minute | LBTIMM

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Urine Analysis Tests

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Result		Units		Reference Range Lower Limit	Reference Range Upper Limit
Blood	=	▼	Result	Select Unit ▼	Limit	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit	Limit

Examination Test or Examination Name	Result		Units	Reference Range Lower Limit	Reference Range Upper Limit
pH	=	▼	Result	Select Unit ▼	Limit
Specific gravity	=	▼	Result	Select Unit ▼	Limit
Urine Micro - WBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - RBC	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Cast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Crystals	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Bacteria	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Yeast	=	▼	Result	Select Unit ▼	Limit
Urine Micro - Parasites	=	▼	Result	Select Unit ▼	Limit
Protein	=	▼	Result	Select Unit ▼	Limit
Glucose	=	▼	Result	Select Unit ▼	Limit
Blood	=	▼	Result	Select Unit ▼	Limit
Nitrite	=	▼	Result	Select Unit ▼	Limit
Leucocytes	=	▼	Result	Select Unit ▼	Limit
Ketones	=	▼	Result	Select Unit ▼	Limit
Bilirubin	=	▼	Result	Select Unit ▼	Limit
Color/appearance	=	▼	Result	Select Unit ▼	Limit
Urobilinogen	=	▼	Result	Select Unit ▼	Limit

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
pH	○	○	○	○	Remark
Specific gravity	○	○	○	○	Remark
Urine Micro - WBC	○	○	○	○	Remark
					Remark

Examination Test or Examination Name	Reference Range Indicator		Clinical Significance		Remark
	Normal	Abnormal	CS	NCS	
Urine Micro - Crystals	☐	☐	☐	☐	Remark
Urine Micro - Bacteria	☐	☐	☐	☐	Remark
Urine Micro - Yeast	☐	☐	☐	☐	Remark
Urine Micro - Parasites	☐	☐	☐	☐	Remark
Protein	☐	☐	☐	☐	Remark
Glucose	☐	☐	☐	☐	Remark
Blood	☐	☐	☐	☐	Remark
Nitrite	☐	☐	☐	☐	Remark
Leucocytes	☐	☐	☐	☐	Remark
Ketones	☐	☐	☐	☐	Remark
Bilirubin	☐	☐	☐	☐	Remark
Color/appearance	☐	☐	☐	☐	Remark
Urobilinogen	☐	☐	☐	☐	Remark

Was physical examination performed? | PEYN

- ☐ Yes
☐ No

Physical Examination Date | PEDAT

Day | PEDATD

Month | PEDATM

Year | PEDATY

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Y

Physical Examination Time | PETIM

Hour | PETIMH

Minute | PETIMM

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Physical Examination Tests

Examination Test or Examination Name	Remark
General Appearance	Remark
Skin/ dermatological	Remark
Head, Ears, Eyes, Nose, and Throat Examination	Remark
Neck/ Thyroid	Remark
Lymphatic	Remark
Cardiovascular	Remark
Respiratory	Remark
Abdomen	Remark
Genitourinary	Remark
Nervous System	Remark
Musculoskeletal	Remark

Examination Test or Examination Name	Remark
Gastrointestinal	Remark
Extremities	Remark
Psychiatric disorders	Remark

Comment | PECOM

Enter comment if any

Were ECG examination assessed? | EGYN

- ☐ Yes
- ☐ No

Reason for not done | EGREAND

Enter Reason for not done

ECG Date | EGDAT

Day | EGDATD Month | EGDATM Year | EGDATY

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M

Y

Y

Y

Y

ECG Time | EGTIM

Hour | EGTIMH Minute | EGTIMM

H

H

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ECG Tests

Examination Test or Examination Name	Result	Units	Reference Range Indicator		Clinical Significance		Remark
			Normal	Abnormal	CS	NCS	
PR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
RR Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QRS Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QT Interval	Result	Select Unit	☐	☐	☐	☐	Remark
QTcF	Result	Select Unit	☐	☐	☐	☐	Remark

ECG Interpretation

Examination Test or Examination Name	Remark
ECG Interpretation	Remark

Comment | ECGOM

Enter Comment

Were Tender/Painful (68) and swollen (66) joint counts assessed? | QSYN

- ☐ Yes
- ☐ No

Reason for not done? | QSREASND

Specify Reason for not done

Has any joint been injected since last visit? | JOININJ

- ☐ Yes
- ☐ No

If yes, please specify joint(s) | JOINSPEC

If yes, please specify joint(s)

Assessment Date | QSDAT

QSDATD | Day

QSDATM | Month

QSDATY | Year

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Y

Tender/Painful (68) and swollen (66) joint counts | TSCOUNT

Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	Temporomandibular	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Sternoclavicular	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Acromioclavicular	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Shoulder	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Elbow	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Wrist	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MCP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Thumb interphalangeal	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Upper extremity PIP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	DIP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐					Hip	☐	☐	☐					
☐	☐	☐	☐	☐	☐	☐	Knee	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Ankle	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Tarsus/Midfoot(feet)	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP1	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	MTP5	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP1	☐	☐	☐	☐	☐	☐	☐	

Left							Joint	Right							
Tender			Swelling					Tender			Swelling				
Present	Absent	ND	Present	Absent	ND	NA		Present	Absent	ND	Present	Absent	ND	NA	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP2	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP3	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP4	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	Lower Extremity Toe PIP5	☐	☐	☐	☐	☐	☐	☐	

ND: Not Done NA: Not Applicable MCP: Metacarpophalangeal joints PIP: Proximal Interphalangeal Joints

DIP: Distal Interphalangeal Joints MTP: Metatarsal Phalangeal Joints Total Tender Present: 0 Total Swallon Present: 0