Table 1 Lab Panel

| Lab Panel: (check one) | Date Collected: | Accession Number: |
| --- | --- | --- |
| CHEMISTRY  HEMATOLOGY  URINALYSIS  Other, specify: | Time Collected:  AM  PM  24-hr clock | Data to be filled out by site |

Indicate the appropriate result for each test

Lipid Laboratory Tests

Table 2 Lipid Laboratory Tests

| Test | Result | Units for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Total Cholesterol (TCHOL) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Low Density Lipoprotein (LDL) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| High Density Lipoprotein (HDL) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Triglycerides (TGs) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Very Low Density Lipoprotein (VLDL) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Lipoprotein(a) [Lp(a)] | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Apolipoprotein A-I (apo A1) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Apolipoprotein B (apo B) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Apolipoprotein E (apo E) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Complete Blood Count (CBC) Laboratory Tests

Table 3 Complete Blood Count (CBC) Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| White Blood Cell Count (WBC) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Lymphocyte Count | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Neutrophil Count (PMNs) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Monocyte Count | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Eosinophil Count | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Hematocrit (HCT) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Hemoglobin (HB) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Platelet Count | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Hemoglobin Electrophoresis | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Electrolyte Laboratory Tests

Table 4 Electrolyte Laboratory Tests

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| Sodium (Na+) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Potassium (K+) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Chloride (Cl-) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Carbon Dioxide (CO2) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Anion Gap | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Blood Urea Nitrogen (BUN) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Creatinine | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Glucose | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Magnesium (Mg2+) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Phosphate (PO4) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Calcium (Ca2+) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Ionized Calcium (iCa2+) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| Bicarbonate (HCO3) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Arterial Blood Gas Laboratory Tests

Table 5 Arterial Blood Gas Laboratory Tests

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| Partial Pressure of Oxygen (PaO2) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Partial Pressure of Carbon Dioxide (PaCO2) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Acidity/ pH | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Liver Function Laboratory Tests

Table 6 Liver Function Laboratory Tests

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| Albumin | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Total Protein | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Aspartate aminotransferase (AST) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Alanine Aminotransferase (ALT) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Total Bilirubin | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Direct Bilirubin | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| Alkaline Phosphatase | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Miscellaneous Chemistry Laboratory Tests

Table Miscellaneous Chemistry Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Lactate Dehydrogenase (LDH) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Lactate | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Iron | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Total Iron Binding Capacity (TIBC) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Ferritin | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Table Autoimmune Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Antinuclear Antibodies (ANA) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Classical AntiNeutrophil Cytoplasmic Antibodies (C-ANCA) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Protoplasmic-staining AntiNeutrophil Cytoplasmic Antibodies (P-ANCA) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Rheumatoid Factor | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Anticardiolipin Antibody IgM (ACA Igm) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Anticardiolipin Antibody IgG (ACA IgG) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| β 2- glycoprotein Antibody IgM | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| β 2- glycoprotein Antibody IgG | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

## Clotting Laboratory Tests

Table Clotting Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Factor V Leiden Mutation (FVL) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Prothrombin Gene Mutation (Factor II/ G20210A) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Protein C Activity | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Protein S Activity | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Activated Protein C Resistance (APCR) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| 5,10 Methylene Tetra Hydrofolate Reductase (MTHFR) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Prothrombin Time (PT) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Activated Partial Thromboplastin Time (aPTT) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Antithrombin Activity (AT-III) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| International Normalized Ratio (INR) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Dilute Russell Viper Venom Time (DRVVT) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Confirmatory Testing for Lupus Anticoagulant | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Fibrinogen | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Plasmin | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| D-dimer | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Thrombin Time | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

## Inflammatory Laboratory Tests

Table Inflammatory Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| High Sensitivity C Reactive Protein (hsCRP) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Erythrocyte Sedimentation Rate (ESR) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Nutrition Laboratory Tests

Table Nutrition Laboratory Tests

| **Test** | **Result** | **Unit for Result** | **Was test result abnormal?** | **If abnormal, Clinically Significant?** |
| --- | --- | --- | --- | --- |
| Vitamin B12 | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Homocysteine | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Folate | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| 25-hydroxy Vitamin D | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Infectious Disease Laboratory Tests

Table Infectious Disease Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Rapid Plasma Reagin (RPR) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| HIV Antibodies | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

## Cardiac Laboratory Tests

Table Cardiac Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Troponin I | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Troponin T | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Creatine Kinase | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Creatine Kinase - Myocardial Bands (CK-MB) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Cerebral Spinal Fluid (CSF) Laboratory Tests

Table Cerebral Spinal Fluid (CSF) Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| CSF Protein | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| CSF Glucose | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| CSF White Blood Cell Count (WBC) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| CSF Red Blood Cell Count (RBC) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Venereal Disease Research Laboratory (VDRL) Slide Test | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Miscellaneous Laboratory Tests

Table Miscellaneous Laboratory Tests

| Test | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- |
| Glycosylated Hemoglobin (HgbA1C) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Creatinine Clearance | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Glomerular Filtration Rate (GFR) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Stool Guaiac | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Toxicology Screen | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Ammonia (NH3) | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Amylase | TBD | TBD | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

Pregnancy Test

Was a pregnancy test performed?  Yes  No (STOP)  Not applicable

Reason Test N/A:  Post-Menopausal  Surgically sterile  Non-surgically sterile  Male

Date Performed:

Test Type:  Blood  Urine

Result:  Positive  Negative

## General Instructions

Laboratory tests are routinely administered in clinical trials of pharmacological interventions to assess subject safety. Laboratory tests may also be used to determine an individual’s eligibility for a study. None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are Exploratory and should be collected for clinical trials when the research team considers them appropriate for their study.

Laboratory results may be received via electronic files directly from central study laboratories or recorded manually on case report forms if the study is using a local lab. In either scenario, it is recommended that the Laboratory Test form be used to record when samples were collected (date and time) so that the laboratory tests results can be matched with the samples collected for each subject.

## Specific Instructions

Please see the Laboratory Tests and Vital Signs for SCI spreadsheet for proposed reference ranges for the tests included on this form.

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Lab Panel – Choose the lab panel that was performed.
* Date and Time Collected –Record the date (and time) the specimen was collected. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Accession Number – Provide the accession number or bar code number that is assigned to the specimen.
* Test – Indicate the name of each laboratory test that is run on the specimen. See the data dictionary for additional information on coding the test name using Logical Observation Identifiers Names and Codes (LOINC).
* Test Performed – Choose one. Indicate whether or not the test was performed on the specimen.
* Result – Record the numeric or alpha-numeric results for each laboratory test.
* Unit for Result – Record the units the numeric results for each laboratory test are measured in. See the data dictionary for additional information on coding the unit of measure using Unified Code for Units of Measure (UCUM).
* Abnormal Result – Choose one. Indicate if the laboratory test result is abnormal. Abnormal means the test result falls outside the normal range.
* Clinical Significance – Choose one. If the laboratory test result is abnormal, indicate if the physician considers the result clinically significant.