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.