Lab Panel Table

| Lab Panel: (check one) | Date Collected | Accession Number: |
| --- | --- | --- |
| CHEMISTRY  HEMATOLOGY  URINALYSIS  Other, specify: | (M M/D D/Y Y Y Y): | Accession Number: |

Indicate the appropriate result for each test.

## Lipid Laboratory Tests

Lipid Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Total Cholesterol (TCHOL) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Low Density Lipoprotein (LDL) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| High Density Lipoprotein (HDL) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Triglycerides (TGs) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Very Low Density Lipoprotein (VLDL) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Lipoprotein(a) [Lp(a)] | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Apolipoprotein A-I (apo A1) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Apolipoprotein B (apo B) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Apolipoprotein E (apo E) | Data to be entered by site | APOE ε2 (rare)  APOE ε3 (most common)  APOE ε4 (high risk) | N/A | Normal  Abnormal  Unknown |

## Complete Blood Count (CBC) Laboratory Tests

Complete Blood Count (CBC) Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| White Blood Cell Count (WBC) | Data to be entered by site | x10^3 | Standard  SI | Normal  Abnormal  Unknown |
| Lymphocyte Count | Data to be entered by site | thousand/microL | Standard  SI | Normal  Abnormal  Unknown |
| Neutrophil Count (PMNs) | Data to be entered by site | thousand/microL | Standard  SI | Normal  Abnormal  Unknown |
| Monocyte Count | Data to be entered by site | thousand/microL | Standard  SI | Normal  Abnormal  Unknown |
| Eosinophil Count | Data to be entered by site | thousand/microL | Standard  SI | Normal  Abnormal  Unknown |
| Hematocrit (HCT) | Data to be entered by site | % | Standard  SI | Normal  Abnormal  Unknown |
| Hemoglobin (HB) | Data to be entered by site | g/dL | Standard  SI | Normal  Abnormal  Unknown |
| Platelet Count | Data to be entered by site | x10^3 | Standard  SI | Normal  Abnormal  Unknown |
| Hemoglobin Electrophoresis | Data to be entered by site | Hemoglobin F (fetal hemoglobin) (HbF)  Hemoglobin A (HbA)  Hemoglobin A2 (HbA2)  Hemoglobin S (HbS)  Hemoglobin C (HbC)  Hemoglobin E (HbE)  Hemoglobin D (HbD)  Hemoglobin H (heavy hemoglobin) (HbH) | N/A | Normal  Abnormal  Unknown |

## Electrolyte Laboratory Tests

Electrolyte Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Sodium (Na+) | Data to be entered by site | mEq/L OR mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Potassium (K+) | Data to be entered by site | mEq/L OR mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Chloride (Cl-) | Data to be entered by site | mEq/L OR mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Carbon Dioxide (CO2) | Data to be entered by site | mEq/L | Standard  SI | Normal  Abnormal  Unknown |
| Anion Gap | Data to be entered by site | mEq/L | Standard  SI | Normal  Abnormal  Unknown |
| Blood Urea Nitrogen (BUN) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Creatinine | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Glucose | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Fasting Insulin | Data to be entered by site | μIU/mL | Standard  SI | Normal  Abnormal  Unknown |
| Magnesium (Mg2+) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Phosphate (PO4) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Calcium (Ca2+) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Ionized Calcium (iCa2+) | Data to be entered by site | mmol/L | Standard  SI | Normal  Abnormal  Unknown |
| Bicarbonate (HCO3) | Data to be entered by site | Meq/L | Standard  SI | Normal  Abnormal  Unknown |

## Arterial Blood Gas Laboratory Tests

Arterial Blood Gas Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Partial Pressure of Oxygen (PaO2) | Data to be entered by site | mmHg | Standard  SI | Normal  Abnormal  Unknown |
| Partial Pressure of Carbon Dioxide (PaCO2) | Data to be entered by site | mmHg | Standard  SI | Normal  Abnormal  Unknown |
| Acidity/ pH | Data to be entered by site | Numeric value | Standard  SI | Normal  Abnormal  Unknown |

## Liver Function Laboratory Tests

Liver Function Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Albumin | Data to be entered by site | g/dL | Standard  SI | Normal  Abnormal  Unknown |
| Total Protein | Data to be entered by site | g/dL | Standard  SI | Normal  Abnormal  Unknown |
| Aspartate aminotransferase (AST) | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |
| Alanine Aminotransferase (ALT) | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |
| Total Bilirubin | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Direct Bilirubin | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Alkaline Phosphatase | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |
| Gamma-glutamyl transpeptidase (GGT) | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |

## Miscellaneous Chemistry Laboratory Tests

Miscellaneous Chemistry Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Lactate Dehydrogenase (LDH) | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |
| Lactate | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Iron | Data to be entered by site | µg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Total Iron Binding Capacity (TIBC) | Data to be entered by site | µg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Ferritin | Data to be entered by site | ng/mL | Standard  SI | Normal  Abnormal  Unknown |

## Autoimmune Laboratory Tests

Autoimmune Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Antinuclear Antibodies (ANA) | Data to be entered by site | Negative  Positive (with numeric value, if positive) | N/A | Normal  Abnormal  Unknown |
| Classical AntiNeutrophil Cytoplasmic Antibodies (C-ANCA) | Data to be entered by site | Negative  Positive (with numeric value, if positive) | N/A | Normal  Abnormal  Unknown |
| Protoplasmic-staining AntiNeutrophil Cytoplasmic Antibodies (P-ANCA) | Data to be entered by site | Negative  Positive (with numeric value, if positive) | N/A | Normal  Abnormal  Unknown |
| Rheumatoid Factor | Data to be entered by site | Negative  Positive (with numeric value, if positive) | Standard  SI | Normal  Abnormal  Unknown |
| Anticardiolipin Antibody IgM (ACA Igm) | Data to be entered by site | MPL units/mL | Standard  SI | Normal  Abnormal  Unknown |
| Anticardiolipin Antibody IgG (ACA IgG) | Data to be entered by site | GPL units/mL | Standard  SI | Normal  Abnormal  Unknown |
| β 2- glycoprotein Antibody IgM | Data to be entered by site | Numeric value | Standard  SI | Normal  Abnormal  Unknown |
| β 2- glycoprotein Antibody IgG | Data to be entered by site | Numeric value | Standard  SI | Normal  Abnormal  Unknown |

## Clotting Laboratory Tests

Clotting Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Factor V Leiden Mutation (FVL) | Data to be entered by site | Absent  Heterozygous (1 allele)  Homozygous (2 alleles) | N/A | Normal  Abnormal  Unknown |
| Prothrombin Gene Mutation (Factor II/ G20210A) | Data to be entered by site | Absent  Heterozygous (1 allele)  Homozygous (2 alleles) | N/A | Normal  Abnormal  Unknown |
| Protein C Activity | Data to be entered by site | % | Standard  SI | Normal  Abnormal  Unknown |
| Protein S Activity | Data to be entered by site | % | Standard  SI | Normal  Abnormal  Unknown |
| Protein S Antigen, Free | Data to be entered by site | % | Standard  SI | Normal  Abnormal  Unknown |
| Activated Protein C Resistance (APCR) | Data to be entered by site | ratio | Standard  SI | Normal  Abnormal  Unknown |
| Prothrombin Time (PT) | Data to be entered by site | seconds | Standard  SI | Normal  Abnormal  Unknown |
| Activated Partial Thromboplastin Time (aPTT) | Data to be entered by site | seconds | Standard  SI | Normal  Abnormal  Unknown |
| Antithrombin Activity (AT-III) | Data to be entered by site | % | Standard  SI | Normal  Abnormal  Unknown |
| International Normalized Ratio (INR) | Data to be entered by site | Numeric value | Standard  SI | Normal  Abnormal  Unknown |
| Dilute Russell Viper Venom Time (DRVVT) | Data to be entered by site | seconds | Standard  SI | Normal  Abnormal  Unknown |
| Confirmatory Testing for Lupus Anticoagulant | Data to be entered by site | ratio | Standard  SI | Normal  Abnormal  Unknown |
| Fibrinogen | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Plasmin | Data to be entered by site | Numeric value | Standard  SI | Normal  Abnormal  Unknown |
| D-dimer | Data to be entered by site | ng/mL | Standard  SI | Normal  Abnormal  Unknown |
| Thrombin Time | Data to be entered by site | seconds | Standard  SI | Normal  Abnormal  Unknown |

## Inflammatory Laboratory Tests

Inflammatory Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| High Sensitivity C Reactive Protein (hsCRP) | Data to be entered by site | mg/L | Standard  SI | Normal  Abnormal  Unknown |
| Erythrocyte Sedimentation Rate (ESR) | Data to be entered by site | mm/hr | Standard  SI | Normal  Abnormal  Unknown |

## Nutrition Laboratory Tests

Nutrition Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Vitamin B12 | Data to be entered by site | pg/ml | Standard  SI | Normal  Abnormal  Unknown |
| Homocysteine | Data to be entered by site | umol/L | Standard  SI | Normal  Abnormal  Unknown |
| Folate | Data to be entered by site | ng/mL | Standard  SI | Normal  Abnormal  Unknown |

## Infectious Disease Laboratory Tests

Infectious Disease Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Rapid Plasma Reagin (RPR) | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| HIV Antibodies | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |

## Cardiac Laboratory Tests

Cardiac Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Troponin I | Data to be entered by site | ng/mL | Standard  SI | Normal  Abnormal  Unknown |
| Troponin T | Data to be entered by site | ng/mL | Standard  SI | Normal  Abnormal  Unknown |
| Creatine Kinase | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |
| Creatine Kinase - Myocardial Bands (CK-MB) | Data to be entered by site | U/L | Standard  SI | Normal  Abnormal  Unknown |

## Cerebral Spinal Fluid (CSF) Laboratory Tests

Cerebral Spinal Fluid (CSF) Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| CSF Protein | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| CSF Glucose | Data to be entered by site | ng/dL | Standard  SI | Normal  Abnormal  Unknown |
| CSF White Blood Cell Count (WBC) | Data to be entered by site | uL | Standard  SI | Normal  Abnormal  Unknown |
| CSF Red Blood Cell Count (RBC) | Data to be entered by site | uL | Standard  SI | Normal  Abnormal  Unknown |
| Venereal Disease Research Laboratory (VDRL) Slide Test | Data to be entered by site | Nonreactive  Weakly reactive  Reactive (with quantitation) | N/A | Normal  Abnormal  Unknown |
| Immunoglobulin G (IgG) | Data to be entered by site | mg/dL | Standard  SI | Normal  Abnormal  Unknown |
| Oligoclonal Bands | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Varicella-Zoster Virus (VZV) Antibodies | Data to be entered by site | Negative  Equivocal  Positive | N/A | Normal  Abnormal  Unknown |
| Varicella-Zoster Virus (VZV) PCR | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |

## Miscellaneous Laboratory Tests

Miscellaneous Laboratory Tests Table

| Test | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Glycosylated Hemoglobin (HgbA1C) | Data to be entered by site | % | Standard  SI | Normal  Abnormal  Unknown |
| Creatinine Clearance | Data to be entered by site | mL/minute | Standard  SI | Normal  Abnormal  Unknown |
| Glomerular Filtration Rate (GFR) | Data to be entered by site | mL/min/1.73m2 | Standard  SI | Normal  Abnormal  Unknown |
| Stool Guaiac | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Ammonia (NH3) | Data to be entered by site | ug of nitrogen/dL | Standard  SI | Normal  Abnormal  Unknown |
| Amylase | Data to be entered by site | units/L | Standard  SI | Normal  Abnormal  Unknown |
| Other, specify: | Data to be entered by site | Data to be entered by site | Standard  SI | Normal  Abnormal  Unknown |

## Toxicology Screen Results

Toxicology Screen Results Table

| Drug | Result | Units for Result | Unit Type | Was test result abnormal? |
| --- | --- | --- | --- | --- |
| Analgesics | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Anticonvulsants | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Barbiturates | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Psychotropics | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Sedatives | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Stimulants | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |
| Sympathomimetics | Data to be entered by site | Negative  Positive | N/A | Normal  Abnormal  Unknown |

## 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 (m m/d d/y y y y):

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.

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 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. 5,10 Methylene Tetra Hydrofolate Reductase (MTHFR) is no longer recommended as a first line test. Homocysteine is preferred.
* Result – Record the numeric or alpha-numeric results for each laboratory test.
* Unit for Result – The recommended units for the numeric results for each laboratory test. For some laboratory tests, result option are included. See the data dictionary for additional information on coding the unit of measure using Unified Code for Units of Measure (UCUM).
* Unit Type – Choose one. Indicate if SI or Standard Units were used.
* Abnormal Result – Choose one. Indicate if the laboratory test result is abnormal. Abnormal means the test result falls outside the normal range.