1. Pregnancy test type: [ ]  Blood [ ]  Urine
2. Pregnancy test result: [ ]  Positive [ ]  Negative
3. Pregnancy Test (β-HCG): blood
4. Pregnancy Test (β-HCG): urine

Indicate the appropriate result for each test

Table 1 Toxicology screen results

|  |  |
| --- | --- |
| Drug | Present? |
| Anticonvulsants | [ ]  Yes[ ]  No[ ]  Unknown |
| Analgesics | [ ]  Yes[ ]  No[ ]  Unknown |
| Sedatives | [ ]  Yes[ ]  No[ ]  Unknown |
| Barbiturates | [ ]  Yes[ ]  No[ ]  Unknown |
| Sympathomimetics | [ ]  Yes[ ]  No[ ]  Unknown |
| Stimulants | [ ]  Yes[ ]  No[ ]  Unknown |
| Psychotropics | [ ]  Yes[ ]  No[ ]  Unknown |
| Other | [ ]  Yes[ ]  No[ ]  Unknown |

Table 2 Electrolyte Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Sodium (Na+) | TBD | TBD |
| Potassium (K+) | TBD | TBD |
| Chloride (Cl-) | TBD | TBD |
| Carbon Dioxide (CO2) | TBD | TBD |
| Anion Gap | TBD | TBD |
| Blood Urea Nitrogen (BUN) | TBD | TBD |
| Creatinine | TBD | TBD |
| Glucose | TBD | TBD |
| Magnesium (Mg2+) | TBD | TBD |
| Phosphate (PO4) | TBD | TBD |
| Calcium (Ca2+) | TBD | TBD |
| Ionized Calcium (Ca2+) | TBD | TBD |
| Bicarbonate (HCO3) | TBD | TBD |
| Fasting Glucose |  |  |
| Fasting Insulin |  |  |
| Urea |  |  |
| Gamma-glutamyl transpeptidase (GGT) |  |  |
| Lactate Dehydrogenase (LDH) |  |  |

Table 3 Lipid Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Total cholesterol (TCHOL) | TBD | TBD |
| Low density lipoprotein (LDL) | TBD | TBD |
| High density lipoprotein (HDL) | TBD | TBD |
| Triglycerides (TGs) | TBD | TBD |
| Very low density lipoprotein (VLDL) | TBD | TBD |
| Lipoprotein (a) [Lp(a)] | TBD | TBD |

Table 4 Complete Blood Count (CBC) Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| White blood cell count (WBC) | TBD | TBD |
| Lymphocyte count  | TBD | TBD |
| Neutrophil count | TBD | TBD |
| Monocyte count | TBD | TBD |
| Eosinophil count | TBD | TBD |
| Hematocrit count (HCT) | TBD | TBD |
| Hemoglobin (HB) | TBD | TBD |
| Platelet count  | TBD | TBD |

Table 5 Arterial Blood Gas Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Partial pressure of arterial oxygen (PaO2) | TBD | TBD |
| Partial pressure of arterial carbon dioxide (PaCO2) | TBD | TBD |
| Arterial base excess value (Be) | TBD | TBD |
| Acidity/pH | TBD | TBD |

Table 6 Liver Function Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Albumin | TBD | TBD |
| Total protein | TBD | TBD |
| Aspartate aminotransferase (AST/ASAT/SGOT) | TBD | TBD |
| Alanine aminotransferase (ALT/ALAT/SGPT) | TBD | TBD |
| Total Bilirubin | TBD | TBD |
| Direct Bilirubin | TBD | TBD |
| Alkaline Phosphatase | TBD | TBD |

Table 7 Clotting Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Prothrombin Time (PT) | TBD | TBD |
| Activated Partial Thromboplastin Time (aPTT) | TBD | TBD |
| International Normalized Ratio (INR) | TBD | TBD |
| Fibrinogen | TBD | TBD |
| Thrombin Time | TBD | TBD |

Table 8 Inflammatory Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| High Sensitivity C Reactive Protein (hsCRP) | TBD | TBD |
| Erythrocyte Sedimentation Rate (ESR) | TBD | TBD |

Table 9 Miscellaneous Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Lactate | TBD |  |
| Glycosylated Hemoglobin (HgbA1C) | TBD | TBD |
| Creatinine Clearance | TBD | TBD |
| Glomerular Filtration Rate (GFR) | TBD | TBD |
| Stool Guaiac | TBD | TBD |
| Ammonia (NH3) | TBD | TBD |
| Amylase | TBD | TBD |

Table 10 Cardiac Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Troponin I | TBD | TBD |
| Troponin T | TBD | TBD |
| Creatine Kinase | TBD | TBD |
| Creatine Kinase - Myocardial Bands (CK-MB)  | TBD | TBD |

Table 11 Cerebral Spinal Fluid (CSF) Laboratory Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| CSF Protein | TBD | TBD |
| CSF Glucose | TBD | TBD |
| CSF White Blood Cell Count | TBD | TBD |
| CSF Red Blood Cell Count | TBD | TBD |

## 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.

The elements on this CRF are classified as Supplemental and should only be collected if the research team considers them appropriate for their study.

## Specific Instructions

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

1. 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).
2. Result – Record the numeric or alpha-numeric results for each laboratory test.
3. Unit for Result – Record the units of 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).