Table 1 Laboratory Tests Information

| Where were the Lab Tests done? | Lab Panel: (check one) | Date and Time Collected: | Accession Number: |
| --- | --- | --- | --- |
| Site Lab  Central Lab | CHEMISTRY  HEMATOLOGY  URINALYSIS  Other, specify: | MM/DD/YYYY  :(HH:MM)  AM  PM  24-hr clock | Data to be filled out by site |

Indicate the appropriate result for each test.

## Complete Blood Count (CBC) Laboratory Tests

Table 2 Complete Blood Count Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| White Blood Cell Count (WBC) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Red Blood Cell Count (RBC) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Mean Corpuscular Volume (MCV) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Absolute Lymphocytes | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Lymphocytes | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Absolute Neutrophil | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Neutrophil Count | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Absolute Monocyte | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Monocyte Count | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Absolute Eosinophils | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Eosinophil Count | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Hematocrit (HCT) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Hemoglobin (HB) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Platelet Count | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Absolute Basophils | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Basophil Count | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Other Chemistry Laboratory Tests

Table 3 Other Chemistry Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Blood Urea Nitrogen (BUN) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Creatinine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Glucose | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Phosphate (PO4) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Calcium (Ca) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Creatine Kinase | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Uric Acid | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Electrolyte Laboratory Tests

Table 4 Electrolyte Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Sodium (Na) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Potassium (K) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Chloride (Cl) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Bicarbonate (HCO3) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Blood Gases

Table 5 Blood Gasses

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| pH | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Partial Pressure of Carbon Dioxide (PCO2) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Partial Pressure of Oxygen (PO2) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Liver Function Laboratory Tests

Table 6 Liver Function Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Pre-Albumin | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Albumin | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Total Serum Protein\* | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Aspartate Aminotransferase (AST) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Alanine Aminotransferase (ALT) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Total Bilirubin | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Gamma-Glutamyl Transferase  (GGT) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Alkaline Phosphatase | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Lipid Laboratory Tests

Was this test done while the participant was fasting? Yes  No  Unknown

Table 7 Lipid Laboratory Tests

| Test | Result | Units for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Total Cholesterol (TCHOL) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Low Density Lipoprotein (LDL) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| High Density Lipoprotein (HDL) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Triglycerides (TGs) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Autoimmune Laboratory Tests

Table 8 Autoimmune Laboratory Tests

| Test | | Result | Unit for Result | Check if Test not Performed | | If “Test not performed,” specify reason | Was test result abnormal? | | If abnormal, Clinically Significant? | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Antinuclear Antibodies (ANA) | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| Rheumatoid Factor | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| Immunoglobulin G | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| Immunoglobulin A | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| Immunoglobulin M | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| Serum Protein EP | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| [GM1](http://neuromuscular.wustl.edu/over/labdis.html#IgGGM1#IgGGM1) Antibody | Negative  Positive, Titer  : | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| GQ1b Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| GT1a Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| [GD1b](http://neuromuscular.wustl.edu/over/labdis.html#gd1b#gd1b) Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| [GD1a](http://neuromuscular.wustl.edu/over/labdis.html#gd1a#gd1a) Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| [GalNAc-GD1a](http://neuromuscular.wustl.edu/over/labdis.html#gngd1a#gngd1a) Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| [Lysoganglioside-GM1](http://neuromuscular.wustl.edu/over/labdis.html#lysogm1#lysogm1) Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| [Sulfatide](http://neuromuscular.wustl.edu/over/labdis.html#sulfatide#sulfatide) Antibody | Negative  Positive, Titer: | | Data to be filled in by site | | Test was not performed | Data to be filled in by site | | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant |
| C-Reactive Protein (CRP) | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |
| Erythrocyte Sedimentation Rate | | Data to be filled in by site | Data to be filled in by site | Test was not performed | | Data to be filled in by site | Abnormal  Normal  Unknown | | Clinically significant  Not clinically significant | |

## Clotting Laboratory Tests

Table 9 Clotting Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Prothrombin Time (PT) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Activated Partial Thromboplastin Time (aPTT) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| International Normalized Ratio (INR) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Endocrine Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Free T4 | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Thyroid-Stimulating Hormone (TSH) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Insulin-like Growth Factor-1  (IGF-1) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Glycosylated Hemoglobin (HgbA1C) | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Cerebrospinal Fluid (CSF) Laboratory Tests

Was CSF testing done? Yes  No  Not applicable

Table 10 Cerebrospinal Fluid Laboratory Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| RBC | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| WBC | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Glucose | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Protein | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Albumin clinical bands | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Pregnancy Tests

Has a pregnancy test been completed**:**  Yes  No  Not applicable

Pregnancy Test - Date Performed: (mm/dd/yyyy)

Pregnancy Test Method: Blood  Urine

Pregnancy Test – Result: Positive  Negative  Not applicable

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

## Urinalysis

Was urinalysis clinical normal?  Yes  No

Table 11 Urinalysis Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Albumin, Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Bacteria | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Bilirubin | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Blood | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Calcium Oxalate Crystals | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Casts | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Glucose, Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Ketones | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Leukocyte Esterase | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Nitrites | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| pH | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Protein, Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| RBCs, Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Culture, Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Specific Gravity | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| Urobilinogen | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |
| WBCs, Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## Urine Chemistry

Table 12 Urine Chemistry Tests

| Test | Result | Unit for Result | Check if Test not Performed | If “Test not performed,” specify reason | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- | --- |
| Creatinine, Random Urine | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnorma  Normal  Unknown | Clinically significant  Not clinically significant |
| Estimated Glomerular Filtration Rate | Data to be filled in by site | Data to be filled in by site | Test was not performed | Data to be filled in by site | Abnormal  Normal  Unknown | Clinically significant  Not clinically significant |

## GENERAL INSTRUCTIONS

Laboratory tests are routinely administered in clinical trials of pharmacological interventions to assess participant/ 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.

Important note: None of the data elements included on this CRF Module are considered Core (i.e., required for all ALS studies to collect). All data elements are considered supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study.

It is important that the study protocol documents detail if a local or central laboratory will perform the laboratory tests.

## 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.
* Data and time specimen 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 data 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 that specimen.
* Result – Record the numeric results or alpha-numeric results for each laboratory test.
* Unit for Result – Record the units the numeric results for each laboratory test are measured in.
* 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.