Lab Panel: (check all that apply)

[ ]  CHEMISTRY

[ ]  HEMATOLOGY

[ ]  URINALYSIS

[ ]  Other, specify:

Date Collected\*:

(m m/dd/yyyy)

Time Collected (24-hr clock): *(please specify)*

Accession Number\*:

Indicate the appropriate result for each test.

## Complete Blood Count (CBC) with Differential and Platelets Laboratory Tests

Complete Blood Count with Differential Platelets Laboratory Tests Data Table

| Test | Test Performed | \*Result | \*Unit for Result | Was test result abnormal\*? | If abnormal, Clinically Significant\*? |
| --- | --- | --- | --- | --- | --- |
| White Blood Cell Count (WBC) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Lymphocyte Count | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Neutrophil Count | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Monocyte Count | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Eosinophil Count | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Hematocrit (HCT) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Hemoglobin (HB) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Glycosylated Hemoglobin (HgBA1C) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Platelet Count | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Vitamin B12 | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

## Electrolyte Laboratory Test

Electrolyte Laboratory Test Data Table

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Sodium (Na) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Potassium (K) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Chloride (Cl) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Carbon Dioxide (CO2) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Anion Gap | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Blood Urea Nitrogen (BUN) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Creatinine | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

Electrolyte Laboratory Test Data Table, continued

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Glucose | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Fasting Glucose | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Fasting Insulin | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Iron | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Total Iron Binding Capacity (TIBC) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Ferritin | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Magnesium (Mg) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Phosphate (PO4) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Calcium | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Ionized Calcium | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Bicarbonate (HCO3) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

Did the participant/ subject fast prior to laboratory testing?

[ ]  Yes [ ]  No

## Lipid Laboratory Tests

Lipid Laboratory Tests Data Table

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Total Cholesterol (TCHOL) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant  |
| Low Density Lipoprotein (LDL) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| High Density Lipoprotein (HDL) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Triglycerides (TGs) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Very Low Density Lipoprotein (VLDL) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Lipoprotein (a) [Lp(a)] | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Apolipoprotein-I(apo A1) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Apolipoprotein B (apo B) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Apolipoprotein E (apo E) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

## Miscellaneous Chemistry Laboratory Tests

Miscellaneous Chemistry Laboratory Tests Data Table

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| C-Reactive Protein | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Frataxin Level | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| GAA repeat-expansion mutation | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Serum N-terminal atrial natriuretic peptide (ANP-N) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Atrial natriuretic peptide (ANP) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| B-type natriuretic peptide (BNP) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Oral glucose tolerance | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Vitamin E | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Lactate | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Troponin I | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Troponin T | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Creatine Kinase | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Creatine Kinase - Myocardial Bands (CK-MB) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Hemoglobin Electrophoresis | [ ] Yes[ ] No | [ ]  HbSS[ ]  HbSA[ ]  HbAA[ ]  HbFF[ ]  HbAF[ ]  HbAT | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

## Liver Laboratory Tests

Liver Laboratory Tests Data Table

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Alanine aminotransferase (ALT) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Aspartate aminotransferase (AST) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Gamma-glutamyl transpeptidase (GGT) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

## Urinalysis

Urinalysis Data Table

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Urine White Blood Cells (WBC) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Urine pH | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Urine Nitrite | [ ] Yes[ ] No | [ ]  Positive[ ]  Negative | TBD | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Urine Creatinine | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

## Oxidative Stress Measures

Oxidative Stress Measures Data Table

| Test | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Urine 8-OH-2-deoxyguanosine/ creatinine ratio | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| 8-OH-2-deoxyguanosine | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| 8-isoprostanes | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |
| Plasma malondialdehyde | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Abnormal[ ]  Normal[ ]  Unknown | [ ]  Clinically significant[ ]  Not clinically significant |

## Pregnancy Tests

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 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 Tracking 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 participant/subject.

Important note: The tests included on this CRF Module that have an asterisk are considered Core (i.e., strongly recommended for all FA clinical studies to collect). The remaining tests (i.e., non Core) are supplemental 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.
* 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 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 the 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.