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.