The form should be used in conjunction with the Laboratory Tests Recommendations Table and Guidelines document.

### Lab Panel: (Choose one)

CHEMISTRY (Blood)

HEMATOLOGY (Blood)

URINALYSIS

Other, specify:

Date Collected:

(m m/dd/yyyy)

Time Collected: (24-hr clock)

Accession Number:

Indicate the appropriate result for each test

Table Laboratory Tests and Tracking

| Test Name | Test Performed | Result | Unit for Result | Was test result abnormal? | If abnormal, Clinically Significant? |
| --- | --- | --- | --- | --- | --- |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |
| Data to be entered by site | Yes  No | Data to be entered by site | Data to be entered by site | Normal  Abnormal  Unknown | Clinically significant  Not clinically significant |

## 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/dd/yyyy)

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.

All CDEs on this form are Supplemental – Highly Recommended for clinical trials.

## 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.
* Result – Record the numeric or alpha-numeric results for each laboratory test.
* Unit for Result – Record the units 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).
* 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.