Table : Lab Panel

| Lab Panel: (Choose one) | Date Collected and Time Collected: | Accession Number: |
| --- | --- | --- |
| [ ]  CHEMISTRY (Blood)[ ]  HEMATOLOGY (Blood)[ ]  URINALYSIS[ ]  Other: | (m m /d d /y y y y ):(h h: m m)[ ]  AM [ ]  PM [ ]  (24-hr clock) | Data to be filled in by site |

Indicate the appropriate result for each test.

Table : Test Results

| Test Name | Test performed? | Result | Units for Result | Was test result abnormal? | If abnormal, clinically significant? |
| --- | --- | --- | --- | --- | --- |
| Urea | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Creatinine | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Aspartate Aminotransferase (ASAT/SGOT) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Alanine Aminotransferase (ALAT/SGPT) | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Total Bilirubin | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Sodium | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Potassium | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Hemoglobin | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Hematocrit | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| White blood cell | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Neutrophils | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Lymphocytes | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Eosinophils | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Platelet | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |
| Other, specify: | [ ] Yes[ ] No | Data to be entered by site | Data to be entered by site | [ ]  Normal[ ]  Abnormal | [ ]  Clinically significant[ ]  Not clinically |

## 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: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are supplemental, frequently used on clinical trials and should 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.*

* 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.