STANDARD Table

T-LB07: Potentially Clinically Significant Laboratory Values

VERSION 2.0

**T2**

| TABLE 14.3\_\_x.x  Potentially Clinically Significant Lab Category  (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  | | ----------------- Test Treatment ------------------ | | |
| Variable (unit)  Criteria# | Control  (N=x)  n/N\_OBS (%) | Arm 1  (N=x)  n/N\_OBS (%) | Arm 2  (N=x)  n/N\_OBS (%) | Total  (N=x)  n/N\_OBS (%) |
|  |  |  |  |  |
| Lab test 1 (standard unit) |  |  |  |  |
|  |  |  |  |  |
| Criterion 1 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Criterion 2 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Criterion ... | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
|  |  |  |  |  |
| Lab test 2 (standard unit) |  |  |  |  |
|  |  |  |  |  |
| Criterion 1 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Criterion 2 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Criterion ... | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
|  |  |  |  |  |
| Lab test ... (standard unit) |  |  |  |  |
|  |  |  |  |  |
| Criterion 1 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Criterion 2 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Criterion ... | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
|  |  |  |  |  |
| Note: The denominator N\_OBS is defined as the number of subjects with at least one post-baseline value for the specific criterion.  # Post-baseline value must be more extreme (worse) than the baseline value to be included in the numerator. If a subject did not have  a baseline value but met the criterion post-baseline then the subject is counted in the numerator. Subject is counted once if the  criterion is met more than once. | | | | |

# Study-Specific Text (to be supplied by Statistician unless otherwise noted)

Analysis Population

Safety Analysis Set

Safety Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lab Category

Chemistry

Hematology

Urinalysis

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment Groups

Control \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Control … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lab test (standard unit): Obtain from data

Criteria for clinical significance for individual lab tests: Obtain from SAP

# Optional Columns and Rows

Test Treatment Total (T2)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Updated Analysis Population options for consistency across all tables  Updated Test Drug to Test Treatment as referenced in eCRF standard |  |