**Verification Plan for QuantiFERON-TB Gold Plus (QFT-Plus)**

|  |  |  |
| --- | --- | --- |
| (Please fill in the table with your laboratory’s information  and details on the method being verified) | | |
| **Instrument/Method/Reagent to be verified:** |  | |
|  | Primary  Back-up | |
| (if applicable)  **Serial Number(s):** |  | |
| **Analyte(s):** |  | |
| **Kit Name:** |  | |
| **Reason for Verification:** | Initial Verification | Re-verification (choose one below)  Instrument move  Instrument modified  Method change  Other: ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Regulatory Status:**  (check all that apply) | FDA Approved  FDA Cleared  CE Marked  EUA  None | |

1. **Overview**
   1. This plan was written using “VAL 3000\_Mycobacteriology Validation Guidelines” as a reference, please refer to this document if more details are needed.
   2. All raw data reports will be saved in (insert location details)
   3. The plan includes the following sections:

* Precision (not required)
* Accuracy
* Analytical Sensitivity and Specificity
* Method Approval
* (Insert/remove additional sections if needed)

1. **Precision**
2. Precision is reproducibility - the agreement of the measurements of replicate runs of the same sample. It is the process of determining the range of random error.
3. DAIDS GCLP guidelines state, *“Precision validation for qualitative tests: Validation of a test’s precision should be performed if the manufacturer’s package insert mentions precision testing AND if value will be gained with such testing.”*

The verification of precision may not add any value for the following reasons:

The qualitative positive/negative results are derived from complex calculations that include precision verification as indicated by the package insert excerpt: *“It is recommended that these packages be used to calculate the regression analysis, the coefficient of variation (%CV) for the standards, and the correlation coefficient (r) of the standard curve.”*

Therefore, precision testing is not required for this assay.

1. **Accuracy**
2. Accuracy is the true value of a substance being measured. Verification of accuracy is the process of determining that the test system is producing true, valid results. Accuracy will be demonstrated using (insert comparison method details such as comparison with a previously verified method, purchased validation/verification panel or past EQA panels).
3. A minimum of 10 positive and 10 negative specimens is acceptable if the results meet the manufacturer’s claims for accuracy as determined in the package insert.

These samples will include.

1. Acceptability criteria: diagnostic sensitivity and diagnostic specificity must meet or exceed manufacturer’s stated claims. Limits of acceptability set by the manufacture should be obtained from the assay package insert and finalized by the Laboratory Director.
2. **Analytical Sensitivity** is the lowest concentration of an analyte that can be measured (also called Lower Limit of Detection). **Analytical Specificity** is the determination of the effect of interfering substances. For an FDA approved, unmodified method the manufacturer’s stated analytical sensitivity and specificity will be used.
3. **Method Approval**- The final decision on methodology verification and acceptance is made after a careful review of all the studies performed as part of the complete method verification process. The Laboratory Director shall make the ultimate decision on method verification. Method acceptance is based on the results from the above studies plus an evaluation of the new method’s cost effectiveness, turn-around-time, laboratory staff training needs, and any other relevant operational considerations.

|  |  |
| --- | --- |
| **Prepared By:** |  |
| **Date:** |  |