**Verification Summary Report for GeneXpert (MTB/RIF, MTB/RIF Ultra, MTB XDR)**

|  |  |  |
| --- | --- | --- |
| (Please fill in the table with your laboratory’s information  and details on the method being verified) | | |
| **Date(s) Verification Performed:** |  | |
| **Laboratory Name:** |  | |
| **City, Country:** |  | |
| **Instrument/Method/Reagent being validated:** |  | |
|  | 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 | |

**Procedure:** Refer to the (insert lab name) Verification Plan for (insert test/method name). This summary was written using “VAL 3000\_Mycobacteriology Validation Guidelines” as a reference, please refer to this document if more details are needed.

**Results:** All raw data reports and statistical analysis can be found in the (insert location details).

1. **Precision** testing for this method is not required for this qualitative method.
2. **Accuracy-** Identify the reference method and materials used to establish accuracy.
   1. Accuracy was demonstrated using (insert comparison method details)
   2. (Describe sample type used for accuracy testing, for example patient samples or EQA panel details)
   3. (Describe number of samples tested for each level, for example 10 positive and 10 negative)
   4. The following tables list the accuracy testing results

|  |  |  |  |
| --- | --- | --- | --- |
| (Enter Name of Method Being Validated) | Diagnostic Sensitivity and Specificity  (Results from Comparison Study) | | **Total** |
| Positive | Negative |
| Positive | # true positive (TP) | # false positive (FP) | TP+FP |
| Negative | # false negative (FN) | # true negative (TN) | FN+TN |
| **Total** | TP+FN | FP+TN | N |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Lab Result (%) | Expected Result (%) | Acceptability |
| **Sensitivity=**  100 x TP/(TP+FN) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |
| **Specificity=**  100 x TN/(FP+TN) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |
| **Positive Predictive Value=**  100 x TP/(TP+FP) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |
| **Negative Predictive Value=**  100 x TN/(TN+FN) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |

1. **Analytical Sensitivity and Specificity-** Refer to test kit package insert. For FDA approved, unmodified tests, manufacturer’s stated sensitivity and specificity will be used.

|  |  |
| --- | --- |
| **Prepared by:** |  |
| **Date:** |  |

**Method Approval**

Approved

Not Approved (provide recommendations/corrective actions below)

Additional comments, if needed:

|  |  |
| --- | --- |
| **Laboratory Director:** |  |
| **Date:** |  |