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

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| (Please fill in the table with your laboratory’s information  and details on the method being validated) | | |
| **Instrument/Method/Reagent to be validated:** |  | |
|  | Primary  Back-up | |
| (if applicable)  **Serial Number(s):** |  | |
| **Analyte(s):** |  | |
| **Kit Name:** |  | |
| **Reason for Validation:** | Initial Validation | Re-validation (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. Precision is not applicable for this method.
4. **Accuracy**
5. 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 validated method, purchased validation panel or past EQA panels).
6. Testing on a minimum of 10 specimens for each expected result will be used (for example, 10 samples resistant for each drug and 10 susceptible samples for each drug). Analytes include the resistance genes that each cartridge can detect. The selection of specimens needs to include resistant and susceptible isolates for each drug that the cartridge can detect.
7. Acceptability criteria:

* Claims in the package insert are based on patient samples and not spiked samples.
* Due to using spiked samples for verification, expect a level of 100% agreement and accept no less than 90% agreement. Any deviations should be explained.
* The test may be considered verified if it meets the requirements initially established for performance by the users of the test and if the sensitivity and specificity are no lower than 5% below those of the reference method, those appearing in peer-reviewed journals, or those claimed by the manufacturer’s marketing data used in the evaluation of test kits and reagents.
* If the sensitivity or specificity of the new or revised test does not satisfy the verification requirements, the test must be considered unverified and corrective action must be taken by the manufacturer, the user, or both. Following corrective action the new or revised test should be run again in parallel with the reference method and interpreted.

1. **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.
2. **Method Approval**- The final decision on methodology validation and acceptance is made after a careful review of all the studies performed as part of the complete method validation process. The Laboratory Director shall make the ultimate decision on method validation. 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.

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