**Validation Plan for Mycobacteria Susceptibility Method**

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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
* 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. Short-term (within-run) and long-term (between-day) precision will be determined by running the negative control and positive control as follows:
   1. Short-term precision will be validated through repetition of isolates to reach categorical agreement for accuracy.
   2. For long-term, H37Rv will be run in triplicate over three days. Isolates will be placed in a different drawer of the MGIT each day, ensuring that all drawers will incubate isolates.
4. Acceptability criteria: Using spiked samples, the acceptability is expected to be 100% growth of mycobacteria samples. Any samples that fail to perform as expected will need to be explained. Below 90% agreement is considered unacceptable.
5. **Accuracy**
6. 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 past EQA panels).
7. A minimum of 20-30 results for each drug that have categorical agreement (for example, 20 results for isoniazid, 20 results for rifampin, etc). The results will include multiple resistant and susceptible results. These samples will include (describe sample details, such as past EQA panels).
8. Acceptability criteria: Using spiked samples, the acceptability is expected to be 100% growth of mycobacteria samples. Any samples that fail to perform as expected will need to be explained. Below 90% agreement is considered unacceptable.
9. **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.
10. **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:** |  |