**Verification Plan for New Mycobacteriology Culture Methods/Assays**

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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:

* Sample Preparation
* Precision
* Accuracy
* Time to Detection (TTD)
* Analytical Sensitivity and Specificity
* Method Approval
* (Insert/remove additional sections if needed)

1. **Sample Preparation** (choose one option)
   1. Spiked samples will be made by using a 0.5 McFarland standard and diluting by 1:10 in sterile distilled water. Media will be inoculated with (insert appropriate volume for the media being validated).
   2. Proven negative sputum samples will be spiked to create samples to be processed in the same way as patient specimens detailed in (insert processing SOP title).
2. **Precision**
3. 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.
4. For qualitative tests, precision will be verified only on analytes that are derived from a quantitative value (The MGIT uses Readable Light Units (RLUs) to determine a positive so precision is required for MGIT but not LJ).
5. Precision testing for this method is:

☐ Required ☐ Not Required (skip to next section)

1. Short-term (within-run) and long-term (between-day) precision will be determined by running H37Rv and (a species of rapid growing mycobacteria) as follows:
   1. For short-term, H37Rv in triplicate, (a non-mycobacteria species such as E. coli), and a negative control containing only phosphate buffer will be set up in one run.
   2. For long-term, H37Rv in triplicate, (a non-mycobacteria species such as E. coli), and a negative control containing only phosphate buffer will be tested once per day for three days. (If verifying MGIT, place samples in a different drawer each day)
2. Acceptability criteria: Using spiked samples, the acceptability is expected to be 100% growth of mycobacteria samples. Any samples that fail to grow or that do not grow in the expected TTD for the species will need to be explained. Below 90% growth is considered unacceptable.
3. **Accuracy**
4. 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 spiked EQA samples)
5. A minimum of 10 samples will be used. These samples will include (describe sample details, such as patient samples, ATCC strains, or EQA panels, along with a breakdown of species. The species used should cover the range of species that the lab expects to encounter during routine testing. Multiple copies of a species can be used, such as Mtb, as long as they are not the same strain or repeated samples. If verifying the MGIT, include a non-mycobacteria species that will not grow, such as E. coli, and a MGIT tube only inoculated with phosphate buffer. These two tubes do not count towards the 10 minimum needed for verification).
6. Acceptability criteria: Using spiked samples, the acceptability is expected to be 100% growth of mycobacteria samples. Any samples that fail to grow or that do not grow in the expected TTD for the species will need to be explained. Below 90% growth is considered unacceptable.
7. **Time to Detection (TTD)**
   1. For precision and accuracy, record the TTD and include that data in the final report in the precision and accuracy sections.
8. **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.
9. **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:** |  |