**Verification Plan for Hain LPA (DRPlus or SL)**

|  |
| --- |
| (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. For short-term, a negative control (insert non-tuberculosis mycobacterium species to be used) and a positive control, H37Rv, will be tested in triplicate in one run.
	2. For long-term, the same negative control and positive control will be tested in triplicate for two additional days for a total of three consecutive days.
4. 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.
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)
7. A minimum of 10 samples for each expected result will be used (for example, 10 samples resistant for each drug and 10 susceptible samples for each drug). These samples will include (describe sample details, such as patient samples, or EQA panels).
8. Acceptability criteria: The diagnostic sensitivity and specificity and positive and negative agreement will be calculated and compared to the manufacturer’s claims. The laboratory values must meet or exceed manufacturer’s stated claims.
9. The manufacturer’s claims for accuracy testing are listed below

|  |  |  |
| --- | --- | --- |
|  | **Smear Positive** **From Manufacturer’s Package Insert** | **Smear Negative****From Manufacturer’s Package Insert** |
| Diagnostic Sensitivity | (00.00%) | (00.00%) |
| Diagnostic Specificity | (00.00%) | (00.00%) |
| Positive Predictive Value | (00.00%) | (00.00%) |
| Negative Predictive Value | (00.00%) | (00.00%) |

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.

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