**Validation Plan for Qualitative 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:** |  |
| **Sample Type(s):** |  |
| **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 1000\_Qualitative 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. The precision is measured in terms of coefficient of variation (CV).
3. For qualitative tests, precision will be validated only on analytes that are derived from a quantitative value (such as optical density) *and* if precision testing is described in the package insert.
4. 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 the negative control and positive control as follows:
	1. For short-term, at least 20 replicates of negative control and at least 20 replicates positive control will be tested in one run each.
	2. For long-term, both negative and high positive control will be tested at least once per day but not more than 5 times per day to obtain a total of 20 replicates each.
2. Acceptability criteria: The (optical densities, or insert other quantitative value as applicable) from the negative and positive controls will be used to calculate the coefficient of variance (CV) and compared to the manufacturer’s claims for reproducibility. The laboratory CV should be less than or equal to the manufacturer’s stated CV.
3. The manufacturer’s claims for precision testing are listed below

|  |  |
| --- | --- |
|  | **From Manufacturer’s Package Insert** |
| Short-term CV | Long-term CV |
| Positive Control | (00.00%) | (00.00%) |
| Negative Control | (00.00%) | (00.00%) |

1. **Accuracy**
2. 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)
3. A minimum of 10 samples for each expected result will be used (for example, 10 positive and 10 negative). These samples will include (describe sample details, such as patient samples, or EQA panels).
4. 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.
5. The manufacturer’s claims for accuracy testing are listed below

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

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