**Validation Summary Report for Qualitative Method**

|  |  |  |
| --- | --- | --- |
| (Please fill in the table with your laboratory’s information  and details on the method being validated) | | |
| **Date(s) Validation Performed:** |  | |
| **Laboratory Name:** |  | |
| **City, Country:** |  | |
| **Instrument/Method/Reagent being 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 | |

**Procedure:** Refer to the (insert lab name) Validation Plan for (insert test/method name). This summary was written using “VAL 1000\_Qualitative Validation Guidelines” as a reference, please refer to this document if more details are needed.

**Results:** All raw data reports and statistical analysis can be found in the (insert location details).

1. **Precision** testing for this method is:

Required  Not Required (skip to next section)

1. (Summarize the materials used for short-term and long-term precision testing, including number of replicates run for each control)
2. The following table lists the precision testing results

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Short-term | | Long-term | | Acceptability |
| Mfg  %CV | Lab Result %CV | Mfg  %CV | Lab Result %CV |
| Positive Control | (00.00%) | (00.00%) | (00.00%) | (00.00%) | (Acceptable) |
| Negative Control | (00.00%) | (00.00%) | (00.00%) | (00.00%) | (Acceptable) |

1. **Accuracy-** Identify the reference method and materials used to establish accuracy.
   1. Accuracy was demonstrated using (insert comparison method details)
   2. (Describe sample type used for accuracy testing, for example patient samples or EQA panel details)
   3. (Describe number of samples tested for each level, for example 10 positive and 10 negative)
   4. The following tables lists the accuracy testing results

|  |  |  |  |
| --- | --- | --- | --- |
| Method being Validated | Diagnostic Sensitivity and Specificity  (Results from Comparison Study) | | **Total** |
| Positive | Negative |
| Positive | # true positive (TP) | # false positive (FP) | TP+FP |
| Negative | # false negative (FN) | # true negative (TN) | FN+TN |
| **Total** | TP+FN | FP+TN | N |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Lab Result (%) | Expected Result (%) | Acceptability |
| **Sensitivity=**  100 x TP/(TP+FN) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |
| **Specificity=**  100 x TN/(FP+TN) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |
| **Positive Predictive Value=**  100 x TP/(TP+FP) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |
| **Negative Predictive Value=**  100 x TN/(TN+FN) | (00.00%) | (Insert manufacturer’s claim) | (Acceptable) |

1. **Analytical Sensitivity and Specificity-** Refer to test kit package insert. For FDA approved, unmodified tests, manufacturer’s stated sensitivity and specificity will be used.

|  |  |
| --- | --- |
| **Prepared by:** |  |
| **Date:** |  |

**Method Approval**

Approved

Not Approved (provide recommendations/corrective actions below)

Additional comments, if needed:

|  |  |
| --- | --- |
| **Laboratory Director:** |  |
| **Date:** |  |