**Validation Summary Report for Urinalysis Dipstick**

|  |  |  |
| --- | --- | --- |
| (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:** |  | |
| **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 plan was written using “VAL 2017\_pSMILE Urinalysis Dipstick 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 not required.
2. **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 (include one set of tables for each analyte).

|  |  |  |  |
| --- | --- | --- | --- |
| 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 or 95%) | (Acceptable/Not Acceptable) |
| **Specificity=**  100 x TN/(FP+TN) | (00.00%) | (Insert manufacturer’s claim or 95%) | (Acceptable/Not Acceptable) |
| **Positive Predictive Value=**  100 x TP/(TP+FP) | (00.00%) | (Insert manufacturer’s claim or 95%) | (Acceptable/Not Acceptable) |
| **Negative Predictive Value=**  100 x TN/(TN+FN) | (00.00%) | (Insert manufacturer’s claim or 95%) | (Acceptable/Not 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.
2. **Reference Ranges** Verification of manufacturer’s stated reference range is not required.

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

**Method Approval**

Approved

Not Approved (provide recommendations/corrective actions below)

Additional comments, if needed:

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