**Validation Plan for Urinalysis Dipstick**

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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 2017\_pSMILE Urinalysis Dipstick 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:

* Accuracy (including Diagnostic Sensitivity and Specificity)
* Analytical Sensitivity and Specificity
* Method Approval
* (Insert/remove additional sections if needed)

1. **Accuracy**
   1. Accuracy is the true value of a substance being measured. Verification of accuracy is the process of determine that the test system is producing true, valid results.
   2. 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 which will most likely be Quality Control but can include known 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 expected results. Results must be equal to, or greater than, the manufacturer’s claims for the method to be considered accurate. If this information is not stated in the package insert, results must be equal to, or greater than, 95%. (State which acceptability criteria will be used: manufacturer’s insert OR 95%)
2. **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.
3. **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:** |  |