

# Standard Operating Procedure

## Title: Documentation Requirement For Micro Test Method Validation

### 5.3.1. Lot Identification Section

5.3.1.1. Identify the lot number(s) of the product or material being evaluated.

5.3.1.2. In cases when the lot number(s) are not available at the time of protocol origination, a comment can be made indicating that the lot numbers are To Be Determined.

5.3.1.3. The lot numbers are to be filled in prior to execution of the approved protocol.

### 5.3.2. Prerequisites Section

5.3.2.1. Identify all prerequisites as defined by technology specific validation procedures (ex. media evaluation, instrument calibration status).

5.3.2.2. Identify all relevant controlled procedures (including version number) necessary for the execution of the defined development of validation studies.

5.3.2.3. Identify any related reports used to support the development or validation studies. This may include development protocols, past validation summary reports, literature review, etc.

5.3.2.4. Identify any training required prior to execution of the approved protocol. This should include, but is not limited to, any procedures being used in draft format.

### 5.3.3. Execution Section

5.3.3.1. Provides any additional general information related to performing the method development or validation.

5.3.3.2. Provides the specific instructions for the performance of the method development or validation studies. Include directions for how many replicates of each test are required.

5.3.3.3. Provides references to specific SOPs for instruction where appropriate.

5.3.3.4. Identifies all quantitative and/or qualitative acceptance criteria for each test performed.

5.3.3.5. Provides directions for recording and record checking of all primary data generated as part of executing the protocol.

### 5.3.4. Deviations

Provide directions on how to document deviations that occur during the execution of the approved protocol.

### 5.3.5. Signature List Section

Documents all personnel involved in the validation of a test method including record checkers. Documents printed name, signature, initials, company / department and date.

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additional pages must be initialled and dated by the laboratory analyst executing the protocol as well as laboratory management.

**5.7.6.** Reports all deviations to originator and/or laboratory management within 2 business days of discovery.

**5.7.7.** Completes all requirements of the protocol. Upon completion provides the protocol to an appropriate Record checker.

### *Record Checker*

**5.7.8.** Second checks all data for accuracy and completeness.

**5.7.9.** Returns executed protocol to analyst for corrections if necessary. Does not approve any incomplete data.

## **5.8. Deviations**

The following guidelines can be used to aid in determining whether a deviation report is needed. These guidelines apply only to deviations related to validation protocols. Deviations associated with the execution of development protocols are handled at the discretion of laboratory management.

**5.8.1.** A deviation report is not required if:

**5.8.1.1.** The entire protocol must be re-executed following a failure requiring additional method development.

The protocol, containing the revised test method, is reissued with an increased version number. If a new protocol template is needed, a validation termination report is issued describing the protocol failure. This incident should be addressed in the final summary report.

**5.8.1.2.** A new protocol is needed because the original protocol was physically destroyed. The protocol should be reissued with an increased version number. If data was generated in the destroyed protocol and can be salvaged, it is transcribed into the new protocol after approval. The transcription must be record checked for accuracy. If data was generated but cannot be salvaged, the studies must be repeated. This incident should be addressed in the final summary report.

**5.8.1.3.** A validation study is terminated for reasons outside the control of the laboratory (ex. validation is cancelled by requestor). A validation termination report is issued to close out the protocol.

**5.8.1.4.** A typographical or editorial error is noted after approval but prior to execution of the protocol. An assessment is to be made as to whether the protocol can be corrected with a lineout or if a new version of the protocol needs to be issued. The originator of the protocol, with the assistance of laboratory management, will decide whether a new protocol is to be issued.