Annex D5

Verification for new IgM EIAs

Note: This document is intended to be used as a template for developing a method verification protocol and summarizing results. Existing entries are intended as guidance and may be changed, deleted, or augmented as needed for the laboratory's specific requirements. Parentheses in blue provide specific examples for appropriate input. Section I of this document provides a record of the Planning and Development stage. Section II provides a summary of results for approval after the validation is performed.

Method Verification Protocol for (insert method name, document number, and document revision)

Protocol Revision Number: (assign a unique revision number for the verification)

Branch/Laboratory: (branch and laboratory name)

Section I: Verification Plan and Protocol

Purpose and Rationale:

To provide objective evidence that the (method name) will meet the laboratory's acceptance criteria and intended use. (method name) provides (quantitative, qualitative, or both quantitative and qualitative) results for the (identification, diagnosis, surveillance, etc…) of (analyte(s)).

Statistical methods defined later in this plan are designed to address the specific needs of the verification. (method name) is an unmodified FDA approved or cleared test. (method name) is expected to perform in accordance with manufacturer's performance specifications.

Method Description/Intended Use:

See the attached manufacturer's package insert for (Method name), document number (manufacturer's document number), and revision number (manufacturer's revision number).

If applicable, include any limiting factors, such as scarcity of samples that will impact the verification parameters. Also include any application(s) of the method that will not be utilized and thus will not be verified.

Acceptance Criteria:

(Record the expected performance specifications provided in the manufacturer's package insert and the expected performance during laboratory use. In many cases, the performance of a test in a laboratory will not match the manufacturer's claims for performance. It is acceptable for the laboratory to establish lower performance specifications. If the manufacturer does not address a specification, record "N/A", but still provide the laboratory specification)

Specification	**Manufacturer's Stated Performance**	**Laboratory Expected Performance**
Accuracy	(enter the percentage)	(enter the percentage)
Precision/ Reproducibility	(enter the percentage)	(enter the percentage)
Reference Interval	Qualitative: (enter whether the analyte is expected to be present or absent in the target population) Quantitative: (enter the range of values that are expected to be seen in the target population)	Qualitative: (enter whether the analyte is expected to be present or absent in the target population) Quantitative: (enter the range of values that are expected to be seen in the target population)
Reportable Range	(enter your the value or range of values as applicable)	(enter your the value or range of values as applicable)
Any other performance characteristic required for test performance	(row may be deleted if not applicable)	(row may be deleted if not applicable)

Sample Requirements:

Required Sample Summary: (rows may be deleted if not applicable)

Total positive samples	#
Total negative samples	#
Sample volume (units**)**	#
Sample matrix	(serum, sputum, spinal fluid, etc.)
Sample matrix	(add rows for each matrix to be verified)

Qualitative Analysis Requirements:

Specification	Number of samples	Planned Calculations
Accuracy	(# of positive samples and # of negative samples) will be measured	$\frac{\#\text{ of correct results}}{\text{total \# of results}} \times 100\%$
Precision/ Reproducibility	(#) of positive samples and (#) of negative samples will be measured in (#) separate runs over at least (# ≥ 3) days	$\frac{\#\text{ of results in agreement}}{\text{total \# of results}} \times 100\%$
Reference Interval	(# of normal population samples) will be evaluated	(manufacturer's suggested range)

Quantitative Analysis Requirements: (table may be deleted if not applicable)

Specification	Number of samples	Planned Calculations
Accuracy	(# of quantifiable samples at specified concentration levels) will be measured	$\frac{\text{result} - \text{true value}}{\text{true value}} \times 100\%$
Precision/ Reproducibility	(# of quantifiable samples at specified concentration levels) will be measured in (#) separate runs over at least (# ≥ 3) days by (# ≥ 2) operators	$\frac{\text{standard deviation}}{\text{measured value}} \times 100\%$
Reference Interval	(# of normal population samples) will be evaluated	$\text{average value} \pm 2\ \text{standard deviation}$
Reportable Range	Quantitative: (# of quantifiable samples at specified concentration levels) will be measured	(linear or polynomial regression)

Origin of Samples:

Sample Material	Source	Description/ Characterization
	(internal or supplier name)	(ATCC Strain #)

Roles and Responsibilities: (Example not intended to be all inclusive)

(Insert name) is responsible for preparing the Method Verification Plan

(Insert name) is responsible for performing the Method Verification

(Insert name) is responsible for Document Management

(Insert name) is responsible for review and approval of the Verification Protocol prior to testing.

(Insert name) is responsible for review and approval of the Verification Protocol upon completion.

Timeline:

Identify expected timeframe for each experiment and establish a timeline for completion of the verification and approval of the method for implementation by the laboratory to report results.

Related Documents:

Document Name	Document Number	Rev. #	Effective date
(Method name) Procedure, if applicable		A	TBD
(Comparison Method name) Procedure, if applicable			

Instrumentation:

Name/Model	Serial/ID#	Cal Date	Cal Due Date

Training Requirements:

Personnel performing the Method Verification are required to complete and document training prior to verification. The following staff are trained and documentation is complete.

Personnel	Type of Training	Date Completed

Section I: Plan and Protocol Approval (prior to testing)

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Name Date: Title: Quality Manager

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Name Date: Title: Team Leader

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Name Date: Title: Laboratory Leader

Section II: Summary Report

Statement of Suitability:

The (method name) is an unmodified FDA approved or cleared test for the (quantitative, qualitative, or both quantitative and qualitative) (identification, diagnosis, surveillance, etc…) of (analyte(s)). The (method name) is designed to be (a stand-alone analysis or in conjunction with confirmatory procedures listed here).

The method verification is applicable to the documents listed within this summary report.

The method verification of (method name) has been completed according to the documented protocol. The (method name) meets all of the acceptance criteria and is approved for use in the (Insert name) Laboratory.

Limitations/Deviations:

(The method is not appropriate to determine…) and/or (The method is not appropriate for use under… …conditions)

Option 1: The verification protocol has been performed a second time without changes to the procedure or protocol. The reason for the retest is…. All data are attached.

Option 2: The verification protocol has been performed a second time using the revised draft of the procedure. The reason for the revision is…. All draft revisions and data are attached.

Option 3: The test performance cannot meet the originally prescribed laboratory expected performance specifications. The acceptance criteria have been adjusted. (Detail the changes to the criteria.) The reason for relaxing the criteria is….The impact of the changes to the method's intended use is….

Summary of Results (Qualitative)

(Copy/Paste the Manufacturer's Stated Performance and the Laboratory Specification/Expected Performance from the Acceptance Criteria table in Section I. Provide the numbers of samples recorded as positive/negative, as well as the total number of samples used in the calculations)

Acceptance Criteria	Manufacturer's Stated Performance	Laboratory Specification/ Expected Performance	Actual Performance
Accuracy	Copy/Paste from Section I	Copy/Paste from Section I	# positive samples out of # measured positive # negative samples out of # measured negative Overall percentage of correct samples: ##%
Precision/ Reproducibility	Copy/Paste from Section I	Copy/Paste from Section I	# positive samples out of # measured by # scientists over # days were in agreement # negative samples out of # measured by # scientists over # days were in agreement Overall percentage of samples in agreement: ##%
Reference Interval	Copy/Paste from Section I	Copy/Paste from Section I	N/A
Reportable Range	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)

Summary of Results (Quantitative)

(Copy/Paste the Manufacturer's Stated Performance and the Laboratory Specification/Expected Performance from the Acceptance Criteria table in Section I. Provide the numbers of samples recorded as positive/negative, as well as the total number of samples used in the calculations)

Acceptance Criteria	**Manufacturer's Stated Performance**	**Laboratory Specification/ Expected Performance**	**Actual Performance**
Accuracy	Copy/Paste from Section I	Copy/Paste from Section I	The average results of # measurements taken is ##, a ##% difference from the expected value ##.
Precision/ Reproducibility	Copy/Paste from Section I	Copy/Paste from Section I	The Coefficient of Variation (CV) for # measurements is ##%.
Reference Interval	Copy/Paste from Section I	Copy/Paste from Section I	Normal range is ## to ##
Reportable Range	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)

Changes to Related Documents:

Document Name	Document Number	Rev. #	Effective date

Samples and Reference Materials:

Material/Matrix	Source/Manufacturer	Characterization	Lot #	Expiration

Additional Equipment:

Name	Serial/ID#	Cal Date	Cal Due Date

Section II: Summary Report Approval

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Name Date: Title: Team Leader

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Name Date: Title: Quality Manager

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Name Date: Title: Laboratory Leader