Inspecting Test Method Verification and Validation—Nonwaived Tests

**Applicable Checklist Requirements: Verification**

**COM.40300** Verification of Test Performance Specifications – FDA-cleared/approved Tests

Prior to clinical use of each unmodified FDA-cleared or approved test, the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

1. Analytical accuracy
2. Analytical precision
3. Reportable range

**COM.40325** Verification of Test Performance Specifications – Tests Approved by an Internationally Recognized Regulatory Authority – Laboratories not Subject to US Regulations

For laboratories not subject to US regulations, prior to clinical use of each test approved by an internationally recognized regulatory authority (e.g., the European Union’s Conformité Européenne (CE) Marking), the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

1. Analytical accuracy
2. Analytical precision
3. Reportable range
4. Any other performance characteristic required to ensure analytical test performance

**Applicable Checklist Requirements: Validation**

**COM.40350** Validation of Test Performance Specifications – Modified FDA-cleared/approved Tests and LDTs

Prior to clinical use of each modified FDA-cleared or approved test and laboratory-developed tests (LDTs), the laboratory has performed a validation study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

1. Analytical accuracy
2. Analytical precision
3. Reportable range
4. Analytical sensitivity (lower detection limit)
5. Analytical specificity
6. Any other performance characteristic required to ensure analytical test performance

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*FDA: US Food and Drug Administration. For laboratories not subject to US regulations, this will refer to national, state, provincial, or local regulatory authority that has governance or jurisdiction of in vitro diagnostic testing.*
Inspecting Test Method Verification—Nonwaived Tests

**Verification**

- Are there records of completed analytical verification? NO → *Cite

  YES → Did the laboratory perform the verification study prior to clinical use of the test? NO → *Cite

  YES → Did the laboratory validate (as applicable):

  - Accuracy using a matrix-appropriate reference method or other established comparative method?
  - Precision within-run and between-run over a period of time?
  - The reportable range?

  - YES

  - NO

  - *Cite

  - Process Exception

  - If a method is verified by someone other than the laboratory’s personnel (e.g., manufacturer’s representative), the laboratory must have records to show that the verification correlates with its in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens.

- Was the testing implemented before June 15, 2009? NO → *Cite

  YES → Laboratory is in compliance

- Was the testing implemented before June 15, 2009? NO → Did the laboratory prepare a written assessment evaluating each component of the test method performance specifications for each test:

  - Acceptability of data?
  - Investigation of discordant results?

  YES → Laboratory is in compliance

  NO → *Cite

- Determine compliance with COM.40475 Method Validation and Verification Approval—Nonwaived Tests

- *Cite: COM.40300 for laboratories subject to US regulations or COM.40325 for laboratories not subject to US regulations

- If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device.
Inspecting Test Method Validation—Nonwaived Tests

Valiation

Are there records of completed analytical validation?

NO

Cite

Cite

YES

Did the laboratory perform the validation study prior to clinical use of the test?

NO

Cite

YES

Did the laboratory validate Analytical Accuracy:

• Using a matrix-appropriate reference method or other established comparative method?
• Using an appropriate number of samples (LDT=quantitative: 20 with concentrations across AMR; quantitative: 20 with concentrations across AMR; qualitative: 20 including pos/neg) or have records of criteria by laboratory director if fewer?

NO

Did the laboratory validate:

• Precision within-run and between-run over a period of time?
• The reportable range over which accuracy was established?

YES

NO

Cite

Did the laboratory validate:

• Analytical sensitivity (lower limit of detection)?
• Analytical specificity (ability to detect the intended target)?
• Any other performance characteristics required to ensure analytical test performance?

YES

NO

Cite

Laboratory is in compliance

Was the testing implemented before June 15, 2009?

NO

YES

Did the laboratory prepare a written assessment evaluating each component of the test method performance specifications for each test:

• Acceptability of data?
• Investigation of discordant results?

YES

Laboratory is in compliance

Determine compliance with COM.40475 Method Validation and Verification Approval - Nonwaived Tests

NO

Laboratory is in compliance

If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device.