

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 (eg, 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

Start: The laboratory implemented a new test, method, or instrument since last inspection, or you have selected an assay to evaluate based on performance issues

Is the test *FDA cleared/
approved or FDA emergency
use authorization (EUA)?

NO

YES

Is the laboratory performing
the test according to the
specifications set forth by
the manufacturer without
any modifications?

NO

Applicable Checklist Requirements: Validation

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

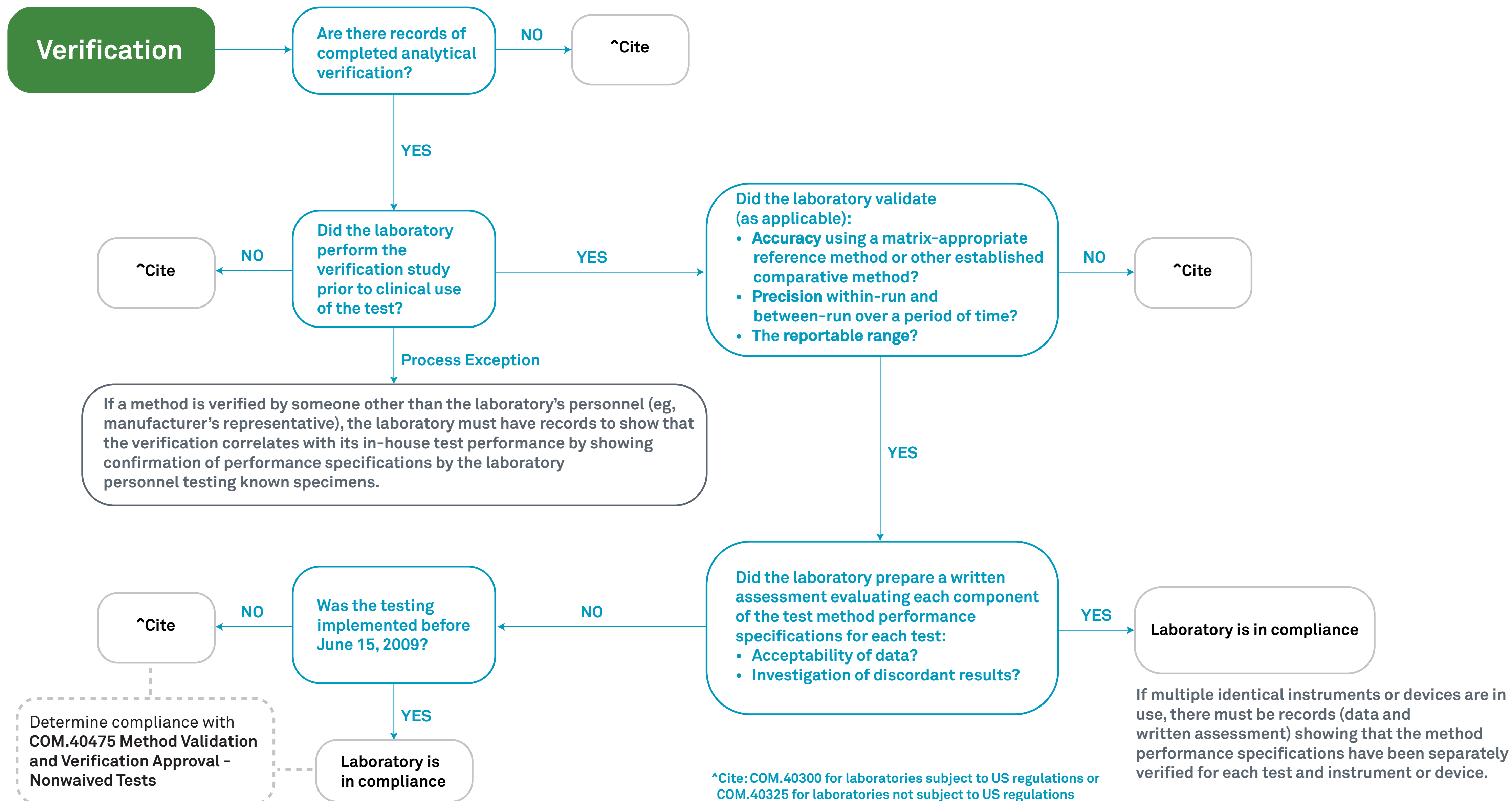
Prior to clinical use of each modified FDA-cleared or approved test and laboratory-developed tests (LDTs), the laboratory has performed a validation study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized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

Proceed to
Verification Flow

Proceed to
Validation Flow

Inspecting Test Method Verification—Nonwaived Tests



Inspecting Test Method Validation—Nonwaived Tests

