

CALIBRATION AND VERIFICATION PROCESSES - WAIVED TESTS

IMM.33337 Calibration, Calibration/Verification - Waived Tests

Phase II



For waived tests, testing personnel follow manufacturer instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:

- ✓ Records for calibration/calibration verification/related functions as required by the manufacturer **AND**
- ✓ Records of recalibration or other appropriate corrective action when calibration verification is unacceptable

CALIBRATION AND VERIFICATION PROCESSES - NONWAIVED TESTS

The requirements in this checklist on CALIBRATION, CALIBRATION VERIFICATION, and ANALYTIC MEASUREMENT RANGE (AMR) VERIFICATION do not apply to waived tests.

This introduction discusses the processes of calibration, calibration verification, and AMR verification.

CALIBRATION: *The process of adjusting an instrument or test system to establish a relationship between the measurement response and the concentration or amount of the analyte that is being measured by the test procedure.*

CALIBRATION VERIFICATION: *The process of confirming that the current calibration settings for each analyte remain valid for a test system.*

Each laboratory must define limits for accepting or rejecting results of the calibration verification process. Calibration verification can be accomplished in several ways. If the manufacturer provides a calibration validation or verification process, it should be followed. Other techniques include (1) assay of the current calibration materials as unknown specimens, and (2) assay of matrix-appropriate materials with target values that are specific for the test system.

ANALYTICAL MEASUREMENT RANGE (AMR): *The range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment that is not part of the usual assay process.*

LINEARITY AND THE AMR

Linearity is a fundamental characteristic of many analytic measurement methods, whereby there is a straight-line relationship between “true” analyte concentrations and measured concentrations. In this context, linearity refers to the relationship between the predicted and observed measurement results and not to the relationship between instrument signal output and analyte concentration.

AMR VERIFICATION

Laboratories are required to verify that the appropriate relationship is maintained over the AMR. Laboratories may verify and use an AMR that is narrower than the range defined by the manufacturer. This may be appropriate when materials available for method validation and/or AMR verification are not available to verify the full range claimed by the manufacturer, or reporting values across the full range defined by the manufacturer is not clinically relevant. For many assays, results beyond the AMR can be reported through dilution or concentration studies (see IMM.33900 & IMM.33910). AMR verification is not required for calculated test results