

(refer to the Definition of Terms in the All Common Checklist) as long as the individual results contributing to the calculation have AMR verification.

Minimum requirements for AMR verification can be met by using matrix appropriate materials, which include low, mid and high concentration or activity range of the AMR with recovery of results that fall within a defined range of the target value. Records of AMR verification must be available.

#### CLOSENESS OF SAMPLE CONCENTRATIONS OR ACTIVITIES TO THE UPPER AND LOWER LIMITS OF THE AMR

When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available. The laboratory director must define limits for accepting or rejecting verification tests of the AMR.

#### IMM.33374 Calibration Procedure

Phase II



**The laboratory calibrates each test system as defined and reviews calibration records for acceptability.**

*NOTE: Calibration of FDA-cleared/approved methods must be performed following the manufacturer's instructions, at minimum, including the number, type, and concentration of calibration materials, frequency of calibration, and criteria for acceptable performance. Calibration procedures are typically specified in the manufacturer's instructions but may also be established by the laboratory.*

##### REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7165 [42CFR493.1217]
- 2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; final rule. *Fed Register*. 2003(Jan 24):3707 [42CFR493.1255]
- 3) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Matrix Effects*. 4th ed. CLSI document EP14. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.
- 4) Miller WG. Quality control. In: Henry's Clinical Diagnostic and Management by Laboratory Methods, 21st Edition, ed McPherson RA, Pincus MR. Saunders Elsevier. 2007;99-111.

#### IMM.33448 Calibration and Calibration Verification Materials

Phase II

**High quality materials with test system and matrix-appropriate target values are used for calibration and calibration verification whenever possible.**

*NOTE: Calibration and calibration verification materials must have defined analyte target values and appropriate matrix characteristics for the clinical specimens and specific assay method. Many instrument systems require calibration materials with system-specific target values to produce accurate results for clinical specimens.*

Suitable materials for calibration verification include, but are not limited to:

1. Calibrators used to calibrate the analytical system
2. Materials provided by the manufacturer for the purpose of calibration verification
3. Previously tested unaltered patient/client specimens
4. Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method
5. Third party general purpose reference materials that are suitable for verification

*In general, routine control materials and proficiency testing materials are not suitable for calibration verification, except in situations where the material has been shown to be suitable (eg, specifically designated by the method manufacturer) or no other materials are available.*

**Evidence of Compliance:**

- ✓ Records of calibration and calibration verification

**REFERENCES**

- 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1255]
- 2) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Matrix Effects*. 4th ed. CLSI document EP14. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

**IMM.33670 Recalibration/Calibration Verification Criteria Phase II**

**Criteria for the frequency and acceptability of recalibration or calibration verification are defined and followed.**

*NOTE: Laboratories must either recalibrate or perform calibration verification at least every six months and if any of the following occur:*

1. At changes of reagent lots unless the laboratory can demonstrate that the use of different lots does not affect the accuracy of patient/client results
2. If QC shows an unusual trend or shift or is outside of acceptable limits, and the system cannot be corrected to bring control values into the acceptable range
3. After major preventive maintenance or change of a critical instrument component
4. When recommended by the manufacturer

*Single use devices, and other test devices that do not allow user calibration, do not require calibration verification.*

**Evidence of Compliance:**

- ✓ Records of calibration verification at defined frequency

**REFERENCES**

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3707[42CFR493.1255(b)(3)]
- 2) Miller WG. Quality control. In: Henry's Clinical Diagnostic and Management by Laboratory Methods, 21st Edition, ed McPherson RA, Pincus MR. Saunders Elsevier. 2007:99-111.

**IMM.33744 Recalibration Phase II**

**The test system is recalibrated when calibration verification fails to meet the established criteria of the laboratory.**

**Evidence of Compliance:**

- ✓ Records of recalibration, if calibration or calibration verification has failed

**REFERENCES**

- 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1255(a)(3)]

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**IMM.33800 AMR Verification Materials Phase II**

**Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials which, at a minimum, include the low, mid and high range of the AMR, and appropriate acceptance criteria are defined.**

*NOTE: The matrix of the sample (ie, the environment in which the sample is suspended or dissolved) may influence the measurement of the analyte. In many cases, the method manufacturer will recommend suitable materials. Other suitable materials for AMR verification include the following:*

1. Linearity material of appropriate matrix, eg, CAP CVL Survey-based or other suitable linearity verification material