

2. Previously tested patient/client specimens, that may be altered by admixture with other specimens, dilution, spiking in known amounts of an analyte, or other technique
3. Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method
4. Patient samples that have reference method assigned target values
5. Control materials, if they adequately span the AMR and have method specific target values.

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 and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion.

Evidence of Compliance:

- ✓ Records of AMR verification at least every six months

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]
- 2) Shah VP, Midha KK, Dige S, et al. Bioanalytical Method Validation - *Pharm Res*. 1992;9(4):588–92.
- 3) Hartmann C, Smeyers-Verbeke J, Massart DL, McDowell RD. Validation of bioanalytical chromatographic methods. *J Pharm Biomed Anal*. 1998;17(2):193–218.
- 4) Findlay JW, et al. Analytical Methods Validation - Bioavailability, Bioequivalence and Pharmacokinetic Studies. *Pharm Res*. 2000;17(12):1551-7.
- 5) Killeen AA, Long T, Souers R, Styler P, Ventura CB, Klee GG. Verifying Performance Characteristics of Quantitative Analytical Systems: Calibration Verification, Linearity, and Analytical Measurement Range. *Arch Pathol Lab Med*. 2014;138(9): 1773-81.

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IMM.33818 AMR Verification

Phase II



Verification of the analytical measurement range (AMR) is performed at least every six months and following defined criteria. Records are retained.

NOTE: The AMR must be verified at least every six months after a method is initially placed in service 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, and the range used to report patient/client test data
2. If QC shows an unusual trend or shift or is outside 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

It is not necessary to independently verify the AMR if the calibration of an assay includes calibrators that span the full range of the AMR, with low, midpoint and high values represented (ie, three points) and if the system is calibrated at least every six months. A one-point or two-point calibration does not include all of the necessary points to verify the AMR.

AMR verification is not required for calculated test results as long as the individual results contributing to the calculation have AMR verification.

AMR verification is not required for methods that measure an analyte quantitatively or semi-quantitatively yet report a qualitative value based on concentration threshold. For such methods, refer to checklist requirement IMM.33905.

Evidence of Compliance:

- ✓ Records of AMR verification, as required, at least every six months

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]