Calibration Verification Q & A

Q. What is “Calibration Verification”?

A. “Calibration Verification” is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC) as “…the assaying of materials of known concentrations in the same manner as patient samples to substantiate the instrument or test system’s calibration through out the reportable range for patient test results.” [1]

Q. Is Calibration Verification really necessary for every test that is being run in my laboratory?

A. The final CLIA ruling concerning certain quality control provisions took effect April 24, 2003 and includes calibration verification. This final ruling states that at a minimum, laboratories must check three points in the reportable range to verify calibration – a low, mid and high point. This must be performed for every laboratory performing unmodified moderate and high complexity testing at least once every six (6) months and whenever any of the following occur:

1. A complete change of reagents for a procedure is introduced.
2. There is major preventive maintenance or replacement of critical parts that may influence test performance.
3. Control materials reflect an unusual trend or shift, or are outside of the laboratory’s acceptable limits,
4. The laboratory’s established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Q. What is AMR Validation, should I be concerned with it, and is this in any way associated with calibration verification?

A. AMR Validation, or analytical measurement range, is the process of confirming that an assay system will accurately measure the concentration or activity of a given analyte over the AMR. The materials used for validation must be known to have matrix characteristics appropriate for the method. The test specimens must have analyte values that, at a minimum, are near the low, midpoint, and high values of the AMR. Specimen target values can be established by comparison with peer group values for reference materials, by assignment of reference or comparative method values, and by dilution ratios of one or more specimens with known values. Each laboratory must define limits for accepting or rejecting validation tests of the AMR. The AMR must be revalidated at least every six (6) months and following changes in lots of analytically critical reagents of major system components.[2]

1 Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1255, (b) (1) (ii).

2 College of American Pathologists (CAP), Calibration and Standards guidelines.