What Is Calibration Verification And How Do I Do It?

On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulations (CLIA) that became effective April 24, 2003. A complete text of these regulations can be found on the Internet at http://www.phppo.cdc.gov/CLIA/regs/toc.aspx.

These regulations now describe how and when calibration verification is to be performed for nonwaived (moderate and high complexity) tests. A test system's calibration must be checked once every six (6) months and whenever any of the following occur:

- All of the reagents used for a test procedure are changed to new lot numbers.
- There is a major preventive maintenance or replacement of critical parts that may influence the test's performance.
- Control materials reflect an unusual trend or shift, or are outside of the lab's acceptable limits.
- The lab has determined that the test system's reportable range should be checked more often.

AUDIT® MicroControls™ now offers your laboratory **MicroCV™ Linearity Sets**, the most complete line of Calibration Verification material designed to assist with your instrument's revalidation. Five unique levels of linearity material are provided with each product to allow for complete monitoring of that
specific test system's reportable range, as defined by the manufacturer.

Our **MicroCV™ Linearity Sets** arrive as either liquid or freeze-dried material (dependent upon the analytes involved). The liquid products are ready to use and testing can begin immediately upon opening the vials. The freeze-dried products must be reconstituted with deionized or distilled water (see package insert for details).

Each of the five levels provided in the linearity set are then run as you would normally run a patient's sample. CLIA regulations do not state the frequency of testing (duplicate, triplicate, etc.) as that should be determined by your laboratory. Once the testing is completed and values are generated, our **AUDITOR™ QC Program** assists your laboratory with the reduction of calibration verification data. Easily accessible via our website (**www.auditmicro.com**), you simply enter the raw data that you collect from your instrument and **AUDITOR™** does the rest! We instantly provide you with an on-line graph of your data, which can either be printed for your records or stored in our secure on-line database for future reference.

Please contact our Technical Service Department at (866) 252-8348 should you have any further questions or need additional information.

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What if Calibration Verification Fails?

AUDIT MicroControls recommends referring to the following check list if your initial calibration verification fails for any specific analyte or analytes:

1. Quality Control Material
    - Are there patterns among controls, e.g. all are below the mean, all are above the mean?
    - Are there any noticeable trends or shift over time?
    - What is the standard deviation (SD) and coefficient of variation (CV) compared to assayed quality control material for the same analyte?
    - What is the standard deviation (SD) and coefficient of variation (CV) compared to a peer group if part of a Quality Control or Quality Assurance program?

2. Acceptable Range
    - Re-examine your laboratory's determination of the acceptable range for calibration verification material.
    - What is your laboratory's current range around the expected target value for that specific analyte in question?

3. How does the accuracy and precision look?

4. Reagent Changes
    - Have there been any changes to your reagent?
    - New lot of reagent?
    - Different manufacturer?
    - New formulation of current reagent (check package insert)?

5. Instrument Maintenance Logs
    - Review daily, weekly, monthly, quarterly, semi-annual and annual logs for any deviations or changes.

6. Environmental
    - Has the instrument been moved recently?
    - Any changes to the environment of the instrument and its surroundings?

7. Servicing
    - Has the instrument been serviced recently?
    - Any software or hardware upgrades or changes?

8. Operation
    - Are there new instrument operators?
    - Any recent modification to the technique in how the assay is run?

9. Comparative Method
    - Is there another nearby laboratory that can also run the calibration verification material to compare results?

If all the above has been performed, and there are still problems, re-calibrate the instrument.

If the instrument still does not perform within laboratory control limits, call the instrument manufacturer for further troubleshooting.