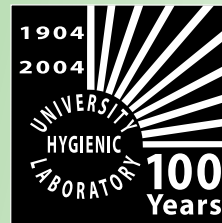


CLIA Corner

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In This Issue...

Calibration vs. Calibration Verification

For this issue of the CLIA Corner, we will define both calibration and calibration verification, and discuss the measures that a laboratory must take to be compliant with the CLIA regulations.

Calibration

Calibration is defined as: *a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.*

When calibrating a test system, the laboratory must at least follow the manufacturer's test system instructions for calibration frequency. If the manufacturer does not specify the frequency of calibration for a test system, or the laboratory finds that the manufacturer's recommended frequency is not adequate, it is the laboratory's responsibility to establish and follow its own calibration procedures.

When establishing calibration frequency, the laboratory must consider the following factors:

- Test system and reagent stability;
- Frequency that the test is performed;
- Technique dependence of the method;
- Frequency of quality control failures; and
- Training, experience and competency of testing personnel.

Once the frequency of the calibration has been established, the laboratory must perform the calibration using "calibration materials" appropriate for the test system, including materials provided or specified by the manufacturer. Calibration materials are defined as solutions that have a known amount of analyte weighted in or has a value determined by repetitive testing using a reference of definitive test method. Again, the laboratory must follow manufacturer instructions by using the correct number, type, and concentration of calibration materials. All calibrations must meet the manufacturer's acceptable limits to be considered successful.

There are a few procedures where calibration requirements do not apply. Examples of such procedures include:

- Manual procedures not involving an instrument [e.g. Kirby-Bauer disk susceptibility tests, tilt-tube prothrombin time test systems, manual ABO group and D(Rho) typing.]
- Microscopic procedures (e.g. KOH preparations, urine sediment analytes, manual differential procedures, and manual cytology screening procedures)
- Procedures involving an instrument in which calibration is not practical

For instruments/test systems that cannot be adjusted (unit use devices), the laboratory must follow the manufacturer's instructions for initial calibration and perform calibration verification as required.

The laboratory must retain calibration records for a minimum of two years. If the test system automatically stores calibration records, the laboratory should perform periodic checks to confirm that the calibration records have been retained. (Some analyzers can only hold a certain amount of data and then will automatically purge the oldest file.)

Calibration Verification

Calibration verification is defined as: *the assaying of materials of a known concentration in the same manner as patient specimens to substantiate the instrument or test system's calibration throughout the reportable range for patient testing results.*

Calibration verification procedures are required on all test systems in which the laboratory performs a calibration and on all factory-calibrated test systems that cannot be calibrated by the user. The laboratory is required to perform calibration verification procedures once every six months or according to the manufacturer's specification whichever is more stringent. When performing calibration verification procedures, the laboratory should use the correct number, type and concentration of materials specified by the manufacturer using at least a minimal (or zero value), a mid-point value, and a maximum value that covers the reportable range of the test system.

The laboratory should also perform calibration verification procedures when any of the following occur:

- There is a complete change of reagents for a test procedure (*Calibration verification is not required if the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient testing results, and control values are not adversely affected by the reagent lot number changes.*)
- There is major preventive maintenance or replacement of critical parts that may influence test performance.
- Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
- The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

There are a variety of materials that are acceptable for the laboratory to use when performing calibration verification procedures. Examples of acceptable calibration verification materials include:

- Commercially available standards or calibration material (*If using calibrators they must be a different lot number than currently in use.*);
- Previously tested proficiency samples;
- Assayed controls; and
- Patient specimens with known values.

For calibration verification materials without an acceptable range, it is the laboratory's responsibility to define acceptable limits for the difference between the measured values obtained, versus the actual concentration of the material. Again, it is important to remember that goal of calibration verification is to test the reportable range of a test system; it is important that the calibration verification materials include a low, mid and high value to represent the reportable range. If the laboratory is having a difficult time finding material to represent a certain value (i.e. low value), it is acceptable to make a dilution from known value of higher concentration.

There are some exceptions to the calibration verification requirements.

- For test systems being calibrated using three or more levels of calibration materials that include a low, mid and high value at least every six months, the calibration verification requirement is considered met.
- For automated cell counters, if the laboratory follows the manufacturer's instructions for instrument operation and tests at least two levels of control materials each day of patient testing the calibration verification requirement is met. (*Note: The control material results must meet the laboratory's criteria for acceptability.*)

- For all other test systems, if the laboratory follows manufacturer's instruction for instrument operation and routinely tests three levels of control materials that include a low, mid and high value more than once each day of testing the calibration verification requirement is met. [*Note: The control material results must meet the laboratory's criteria for acceptability and the control materials must be traceable to the National Institute of Standards and Technology (NIST) reference materials.*]
- For blood gas analysis, the laboratory must perform calibration and calibration verification procedures in accordance with the manufacturer's instructions. [*Note: If the blood gas analyzer performs other analytes (i.e. electrolytes, hemoglobin), calibration verification procedures are required for those analytes.*]

If the calibration verification fails, the laboratory should repeat the test systems calibration procedure. Once the calibration is acceptable, it is good laboratory practice to run controls before resuming patient testing. If the test system is factory-calibrated, and the calibration verification is unacceptable, contact the manufacturer of the test system.

References

Centers for Medicare and Medicaid Services; *Appendix C - Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services*; published January 12, 2004.



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