Clinical Laboratory Improvement Amendments (CLIA)

Calibration and Calibration Verification

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. While every effort has been made to ensure the accuracy of this restatement, this brochure is not a legal document. The official CLIA program requirements are contained in the relevant law, regulations and rulings. Please note that state, local, and accreditation requirements may be more stringent.

What is the difference between calibration and calibration verification?

Calibration means 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.

Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

Which laboratories are required to perform calibration and calibration verification?

In general, laboratories using non-waived test systems are required to perform calibration and calibration verification. It is not a requirement for waived test systems, unless required in the manufacturer's instructions.

Calibration

Do I need to record and retain documentation each time I perform calibration?

Yes, it is a regulatory requirement to retain documentation for two years.

Is calibration required for every procedure my laboratory performs?

No, calibration is not required for the following:

- Manual procedures not involving an instrument;
- Microscopic procedures; and
- Test systems which include instruments that cannot be adjusted or calibrated because they are factory or manufacturer calibrated.

How do I perform calibration?

The manufacturer's instructions for the test system should describe the process for performing calibration, as well as when and how often it is to be performed. Laboratories must follow the manufacturer's instructions for performing the calibration and must follow or exceed the manufacturer's frequency recommendations for calibration.

What materials should I use to perform calibration?

The manufacturer's instructions for the test system should specify the number, type and concentration of the calibration material to use.

Calibration material is a solution that contains a known amount of analyte. Calibration materials must be appropriate for the test system and, if possible, traceable to a reference method or reference material of known value. In the past, the term "standard" was generally used to mean calibration material.

Calibration Verification

Do I need to record and retain documentation each time I perform a calibration verification?

Yes, it is a regulatory requirement to retain documentation for two years.

When must I verify a test system's calibration?

Once every 6 months (or more frequently if specified in the manufacturer's instructions) and whenever any of the following occur:

- All of the reagents used for a test procedure are changed to new lot numbers, **unless** the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are also not adversely affected by reagent lot number changes.
- There is major preventive maintenance or replacement of critical parts that may influence the test's performance. This includes when the laboratory sends a test system to the manufacturer for repairs. The laboratory must check the calibration of a repaired test system before resuming patient testing and reporting results.
- 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 has determined that the test system's reportable range for patient test results should be checked more frequently.

What materials should I use to perform calibration verification?

A variety of materials with known concentrations may be used to verify calibration, for example, commercially available standards or calibration materials, proficiency testing samples with known results, control materials with known values, or patient specimens with known values.

Since the purpose of calibration verification is to check whether the test system is providing accurate results throughout the reportable range, three levels should be tested—one at the high end of the reportable range, one at the low end of the reportable range, and one near the midpoint of the reportable range.

Are there exceptions to calibration verification requirements?

Yes, there are exceptions:

- Instruments that are factory or manufacturer calibrated do not require calibration verification
- Tests that are considered non-quantitative (e.g., Prothrombin Time (PT) and Activated Clotting Time (ACT), which are measured in units of time) do not require calibration verification
- For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation, and tests two levels of control materials each day of testing, provided the control results meet the laboratory's criteria for acceptability.
- For automated chemistry analyzers, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and routinely tests three levels of control materials (lowest level available, mid-level, and highest level available) more than once each day of testing, the control material results meet the laboratory's criteria for acceptability and the control materials are traceable to National Institute of Standards and Technology (NIST) reference materials.
- If the test system's calibration procedure includes three or more levels of calibration material, and includes a low, mid, and high value, and is performed at least once every six months, then the requirement for calibration verification is also met.

What should I do if calibration verification fails?

If calibration verification results are unacceptable, you must repeat the test system's calibration procedure. If after recalibration there are still issues, the laboratory must take corrective action(s) and document this activity.

Is there a difference in the requirements for calibration and calibration verification based on the complexity of the test system?

No. The CLIA calibration and calibration verification requirements are the same for all non-waived test systems.

Where can I find additional information about the CLIA requirements pertaining to calibration and calibration verification?

State Operations Manual: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf

Where can I get additional information?

For additional information, you can email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov

CLIA Law & Regulations:
https://www.cdc.gov/clia/law-regulations.html

CDC CLIA website:
https://www.cdc.gov/clia/index.html

FDA CLIA website:
https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia