

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:

- Control activities routinely used to satisfy the CLIA requirements at §493.1256 do not satisfy the calibration verification requirements. However, there is an exception for automated cell counters. 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.
- 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. After repeating the calibration procedure, it is good laboratory practice to run controls before resuming patient testing.

If the test system is factory-calibrated, consult with the manufacturer of the test system.

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 nonwaived test systems.

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

Refer to "The State Operations Manual," Appendix C—Interpretive Guidelines, Calibration and calibration Verification Procedures (§493.1255) available on the CMS website at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp

FDA: www.fda.gov/cdrh/CLIA/index.html (for a listing of waived, moderate complexity and high complexity tests).

Clinical Laboratory Improvement Amendments (CLIA)

Calibration and Calibration Verification

Brochure #3

What is calibration, and how do I do it?

*Information to assist your laboratory in meeting this
CLIA requirement for nonwaived
(moderate and high complexity) test systems!*

NOTE: 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 summary of updated requirements pertaining to calibration and calibration verification is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at <http://www.phppo.cdc.gov/CLIA/regs/toc.asp>.



What is the difference between calibration and calibration verification?

Calibration is the process of testing and adjusting the instrument or test system readout to establish a correlation between the instrument's measurement of the substance being tested and the actual concentration of the substance.

Calibration verification means testing materials of known concentration in the same manner as patient specimens to assure the test system is accurately measuring samples throughout the reportable range.

Calibration

Is there a new requirement for calibration?

No, the CLIA requirements for calibration have not changed. The laboratory is responsible for performing calibration as directed by the manufacturer's test system instructions, and when calibration verification of the test system (see below) does not produce acceptable results.

Reminder: Be sure to document in the laboratory's records **each** time you perform calibration.

Is calibration required for every procedure my laboratory performs?

No, calibration is not required for the following:

- Manual procedures—such as microbiology cultures and tilt-tube prothrombin time test systems.
- Microscopic procedures—such as KOH preparations, pinworm preparations, urine sediment analysis, all manual cell differential procedures, and manual cytology screening procedures.
- Procedures involving an instrument in which calibration is not practical—such as prothrombin procedures.

How do I perform calibration?

The test system's instructions should describe the process for performing calibration, as well as when and how often it is to be performed.

What materials should I use to perform calibration?

The test system's instructions 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. In the past, the term "standard" was generally used to mean calibration material.

Calibration Verification

Is there a new requirement for calibration verification?

No, the laboratory has always been responsible for calibration verification or "checking" calibration. However, the process for checking a moderate complexity test system's calibration was not defined. The regulations now describe how and when calibration verification is to be performed for nonwaived (moderate and high complexity) tests.

Reminder: Be sure to document in the laboratory's records **each** time you perform calibration verification.

When must I check a test system's calibration (perform calibration verification)?

Once every 6 months (or more frequently if specified in the test system'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 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.

Reminder: The laboratory **is** responsible for verifying calibration on factory-calibrated test systems that cannot be calibrated by the user.

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