CLIA Corner

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Calibration Verification Requirements & Exceptions

What is calibration verification?

Calibration verification is 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 test results.

When is calibration verification necessary?

Calibration verification procedures are required on test systems in which the laboratory performs a calibration. The laboratory is required to perform calibration verification procedures once every six months or according to the manufacturer's specifications, whichever is more stringent. When performing calibration verification procedures, the laboratory must use the correct number, type and concentration of materials. Calibration verification should include at least three levels of known materials, including: a minimal (or zero value), a mid-point value, and a maximum value that covers the reportable range of the test system.

The laboratory must 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.

What materials can be used to perform calibration verification procedures?

There are a variety of materials that are acceptable for the laboratory to use when performing calibration verification procedures which include, but are not limited to:

- Commercially available standards or calibration material (*If using calibrators they must be of a different lot number than currently in use);*
- Previously tested proficiency samples (PT) *(PT samples can only be used after the event submission deadline);*

- Assayed controls; and
- Patient specimens with known values.

If the laboratory chooses to use materials like previously tested PT samples, calibrators or patient specimens, it is the laboratory's responsibility to define acceptable ranges. The laboratory must determine the acceptable difference between the measured values obtained versus the actual concentration of the materials.

The goal of calibration verification is to test the reportable range of the test system; it is important that the calibration verification materials include a low, mid and high value representative of the reportable range. If the laboratory is having difficulties finding material to represent a certain value (i.e. low value), it is acceptable to make a dilution from a known value of higher concentration.

What are the exceptions for performing calibration verification?

There are a few exceptions to the calibration verification requirements. Calibration verification is not necessary if your test system meets one of the following four exceptions:

1. If the laboratory calibrates a test system and/or analyte at least every six months using three or more levels of calibration materials (which include a low, mid and high value), calibration verification procedures are considered met.
2. For automated cell counters (hematology analyzers), 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 considered met. (*Note: This exception does not apply to centrifugal hematology test systems*.)
3. For automated chemistry analyzers, if the laboratory follows 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 calibration verification requirement is considered 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.]*
4. **Calibration verification is not required on:**
    - **Instruments that are factory or manufacturer calibrated (i.e. microalbumin testing performed on Afinion) and/or**
    - **Tests that are considered non-quantitative (i.e. hepatitis B surface antibody testing)**

Please remember the laboratory must follow manufacturer's instructions, if they are more stringent that the CLIA regulations, when performing calibration verification. Therefore, if the test system meets one of the exceptions, but the manufacturer requires calibration verification, the laboratory will be expected to perform calibration verification procedures.

Is calibration verification required on blood gas analyzers?

For blood gas analysis, the laboratory must perform calibration and calibration verification procedures in accordance with the manufacturer's instructions. If the laboratory meets that manufacturer's instructions for calibration and calibration verification, the laboratory does not have to adhere to the calibration and calibration verification requirements. [Note: If the blood gas analyzer performs other analytes (i.e. electrolytes, hemoglobin, ionized calcium), calibration verification procedures are required for those analytes.]

Provider-Performed Microscopy (PPM) Procedures Workbook

The Centers for Disease Control and Prevention (CDC) recently released a new workbook for PPM procedures. The workbook states:

"Provider-performed microscopy (PPM) procedures are a select group of moderately complex microscopy tests commonly performed by health care providers during patient office visits. Tests included in PPM procedures do not meet the criteria for waiver because they are not simple procedures; they require training and specific skills for test performance. A CLIA Certificate for PPM procedures allows physicians, midlevel practitioners, and dentists to perform certain moderate complexity microscopic examinations in addition to waived testing during a patient's visit. Controls are generally not available to monitor the complete testing process for these procedures. Therefore, only limited activities are suitable for inspection. The laboratory or testing site performing PPM procedures is not subject to routine biennial inspections. However, a CLIA certificate is required and the laboratory or testing site must meet the CLIA quality standards for moderate complexity testing."

This book is an excellent resource in determining the CLIA quality standards in performing PPM procedures. An electronic version of the PPM workbook can be found at: http://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020-A_Stang_PPMP_Booklet_FINAL.pdf.

Laboratories may also contact the CDC directly at PPMP@cdc.gov or by calling 404-498-2290 to receive a hard copy of the workbook.