The University of Iowa | State Hygienic Laboratory

CLIA CORNER

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In This Issue…

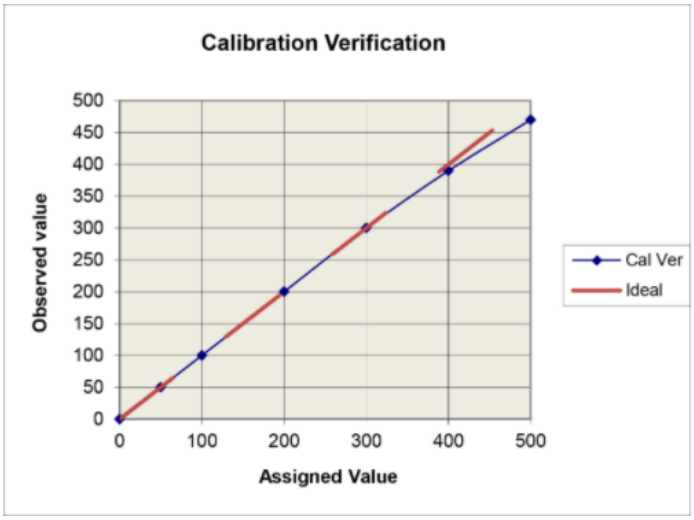
Calibration and Calibration Verification Procedures for Non-waived Test Systems

Clinical Laboratory Improvement Amendments

For non-waived test systems, calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. In this issue of the CLIA Corner, we'll discuss the difference between calibration and calibration verification as well as the requirements for each.

What is the difference between calibration and calibration verification?

Calibration is the process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of substance that is being measured by the test procedure. Essentially, the laboratory and/or manufacturer uses materials of known concentration to set the instrument so that you get the "right" answer when running a test.



Calibration Verification is 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. To be more concise, the laboratory uses materials of known concentration to verify that the instrument is set correctly. No adjustments should be done with the verification. If the calibration verification Is not acceptable, the laboratory will need to perform a calibration to adjust the calibration curve. This assures that the test system is accurately measuring samples throughout the reportable range.

Calibration

Calibration is performed and documented:

1. With at least the frequency recommended by the manufacturer; and
2. Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

Requirements:

* The laboratory must follow the manufacturer's test system instructions, using calibration materials provided or specified;
* Calibration materials used must be appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and
* The laboratory's verified or established calibration criteria must include the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration.

Exceptions:

The calibration requirements do not apply to several procedures, which include, but are not limited to:

⇒ Manual procedures not involving an instrument *(e.g., microbiology cultures, lateral flow kit tests, Kirby-Bauer disk susceptibility tests, ABO group and D (Rho) typing);*

⇒ Microscopic procedures *(e.g., KOH preparations, urine sediment examinations, all manual differential procedures, manual cytology screening procedures);* and

⇒ Test systems which include instruments that cannot be adjusted or calibrated because they are factory or manufacturer calibrated *(e.g. unit use devices)*. This includes instruments that utilize a whole blood specimen and single unit use cartridge *(e.g., Activated Clotting Time).*

Notes:

* Test system calibration procedures must follow the manufacturer's instructions for carrying out the calibration and must follow or exceed the manufacturer's frequency recommendations for calibration. However, if a calibration system proves to be less stable than expected by the manufacturer, additional calibration materials and/or more frequent calibration may be required.

Calibration Verification

Calibration verification is performed and documented:

1. At least once every six months or according to the manufacturer's recommendations, whichever is more stringent;
2. Whenever a complete change of reagents for a procedure is introduced *(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)*;
3. Whenever there is major preventative maintenance or replacement of critical parts that may influence performance;
4. Whenever control materials reflect an unusual trend or shift, are outside the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem; and
5. Whenever the laboratory's established schedule for verifying reportable range for patient test results requires more frequent calibration verification.

Calibration Verification, continued...

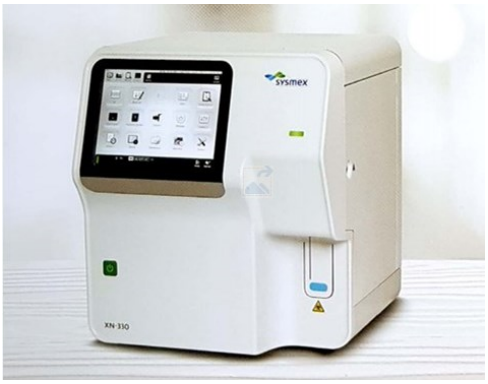
Requirements:

- The laboratory must follow the manufacturer's calibration verification instructions; and
- The laboratory must have verified or established criteria for calibration verification that includes:
  - The number, type, and concentration of materials, as well as acceptable limits for calibration verification; and
  - At least a minimal (or zero value), a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range for the test system.

Exceptions:

Calibration verification is **not** required for the following:

- 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- point and high value), calibration verification procedures are considered met;



- For automated cell counters *(e.g., 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)***;
- 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)***;
- Instruments that are factory or manufacturer calibrated; and
- Tests that are considered non- quantitative *(e.g., prothrombin time and lateral flow test kits).*

NOTE: If the manufacturer's instructions for calibration verification are more stringent than the CLIA regulations, the laboratory must perform calibration verification according to the manufacturer, even if the test system meets one of the exceptions above.

Calibration Verification Materials:

A variety of materials can be used to perform calibration verification including, but not limited to, the following:

⇒ Commercially available standards or calibration material **(If using calibrators they must be of a different lot number than currently in use)**;

⇒ Previously tested proficiency testing (PT) samples **(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 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 and the actual concentration of the materials.
- If the laboratory is unable to find material that represents a certain value (i.e. low value), it is acceptable to make a dilution from a known value of higher concentration.

If you would like your name added to our CLIA Corner google group, send an email to:

Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu

Send us your CLIA questions!

For a future issue of the CLIA Corner, we'd like to use a Question & Answer format and would appreciate your help. Please email your questions to Kristi or Melinda and include "CLIA Corner Question" in the subject line.

Laboratory Humor