COLA Clinical Laboratory Accreditation

COLA Primers Accreditation

COLA PRIMER 15

Calibration Verification

● Introduction ●

For non-waived quantitative tests and test systems that require calibration, laboratories are required to calibrate according to the manufacturer's instructions, or more frequently if specified by the Laboratory Director. Calibration is also performed after major instrument maintenance, to resolve QC failures, or troubleshoot other problems with the assay. Calibration "sets" the test system by using calibrators of known value.

Calibration verification is a procedure for testing samples with known values, just like you would test a patient specimen, in order to confirm that the calibration is still valid. You must use at least three samples across the reportable range of the assay, such as samples with a low, a mid-point, and a high value. If the values fall within expected ranges, then the calibration verification passes, and demonstrates that the assay is accurate across the reportable range.

● Frequency ●

Calibration verification must be performed at least every six months. There are exceptions, and these are covered in the next section of this document. Calibration verification may be required more frequently than every six months if:

- The manufacturer requires more frequent calibration verification or
- The laboratory has determined that, based on the test performance in the laboratory, the calibration should be checked more frequently.

You should also perform calibration verification after minor instrument maintenance. As noted above, major instrument maintenance should be followed by a full calibration of the assay.

Your laboratory may also want to perform calibration verification to troubleshoot QC problems. It is generally not necessary to perform calibration verification when implementing a new lot number of reagents, unless this is required by the manufacturer. It is recommended that when you first initiate a new test, you perform calibration verification with each new lot, until you are satisfied that the performance lot-to-lot is consistent. QC must always be run with a new lot number of reagents.

● Are There Exceptions? ●

The requirement for calibration verification is considered met if the test system's calibration procedure for the analyte uses three or more non-zero levels of calibration material AND:

- Calibrators used represent low, mid-point, and high values and
- Is performed at least every six months.

For instruments that are factory calibrated and do not allow user calibration, calibration verification is not required. For these test systems, consult the manufacturer for guidance if QC fails and you are unable to identify and resolve the problem.

Calibration verification requirements for automated hematology cell counters are considered met if the laboratory:

- Follows the manufacturer instructions for instrument operation;
- Tests at least two levels of QC materials each day of testing; and
- Obtains acceptable results for the daily QC.

For screening assays that are reported as qualitative (positive or negative) based on a threshold or cutoff, the calibration verification requirement is met if the laboratory has verified the accuracy of the assay at the cutoff level at least every six months. This is done by verifying values at the cutoff, slightly above the cutoff, and slightly below the cutoff threshold, according to the laboratory's approved procedure.

● Calibration Verification Materials ●

Calibration verification is performed by running samples with known values just like you would run patient specimens. You must use at least one sample with a known low, a known mid-point, and a known high value for the test. Several different types of materials can be used for this purpose.

First, there are commercially available calibration verification materials from companies that specialize in this area. You can also use Proficiency Testing samples from previous PT events, using the acceptability ranges that came with your PT report for these samples. It is also acceptable to use QC materials, as long as they are not the same lot number of QC that you are currently using for daily QC.

Previously tested patient specimens can also be used but is not the preferred material for calibration verification. If you use previously tested patient specimens, your laboratory must establish acceptable ranges, using a +/- 2SD range or a set percentage range. It is sometimes hard to identify and maintain ample supplies of patient specimens at or near the low end of the reportable range and at or near the high end of the reportable range.

In order to assess the accuracy of the results obtained, it is important to ensure the measured value is a fine value as opposed to a less than or greater than result.

● Performing Calibration Verification ●

To perform calibration verification:

- Using a form such as the one attached to this Primer, record the date, analyte and the calibration verification materials used.

- Run at least three levels (low, mid-point, and high) and document the results. One repetition for each level is adequate, but some labs choose to run in duplicate or triplicate. You should follow your laboratory's calibration verification procedure.
- Evaluate the accuracy of the results obtained. This can be done by comparing the results to the acceptable range for the materials used or following acceptability criteria established by your laboratory director.
- According to your laboratory's procedure, document whether the calibration verification is acceptable.

● Investigating Failed Calibration Verification ●

If one or more of the levels does not fall within the acceptable range, then calibration verification is not acceptable. You should then review the QC, maintenance, and reagents to see if you can determine the cause of the failure. If you are able to identify a problem, you should then re-run your calibration verification and QC to verify that the corrective action was effective.

You may need to calibrate the assay if your calibration verification fails. Be sure to run QC after calibration.

● Documentation ●

You must keep detailed records of all calibration verification events and maintain them for at least two years. This includes not only the calibration verification form, such as the one attached, but raw data such as instrument print-outs, as well as all documentation of corrective action taken as a result of failed calibration verification.

If you use commercially available calibration verification materials, you will run the samples in the kit and submit the results to the vendor, who will then send you a report.

All calibration verification reports, either a manual form such as the one attached, or a report generated by a vendor, must be reviewed and signed by the Laboratory Director or designee.

CALIBRATION VERIFICATION

Test _____ Current reportable range_____

Instrument_____ Calibration Verification Materials used_____

Date	Tech	Three Point Calibration Verifier Values									Acceptable Y/N	Corrective Action Taken (if necessary)
		LOW			MID-POINT			HIGH				
		Verifier value	Measured Value	+/- % Range	Verifier value	Measured Value	+/- % Range	Verifier value	Measured Value	+/- % Range		

NOTE: Also keep any instrument tapes or printouts with calibration verification records.