COLA Clinical Laboratory Accreditation

COLA Primers Accreditation

COLA PRIMER #52

New QC Lot Number Verification/Establishing Acceptable QC Ranges

• Introduction •

Quality Control (QC) is essential to the clinical laboratory, as it ensures that laboratory results are both precise and accurate. Most non-waived laboratory instrumentation requires daily testing of external QC; that is, commercially available controls with known values for each analyte.

When quality control materials are purchased separately from the test reagents, such as for automated Hematology, Coagulation, Chemistry, and Immunochemistry test systems, the laboratory must verify each new lot of these controls by repeated testing, prior to putting them into use. This is a regulatory requirement and can be found under QC 8 in the COLA Accreditation manual.

Note: This requirement does not apply to single use test devices, or to test systems where the controls and reagents come packaged together as a unit to be used together with no interchanging of materials among kits or lot numbers.

Why verify new control lots?

Because external controls are used to test that the reagents and instruments are operating correctly, it's important that all new control lots are checked to be sure that *they themselves* are within parameters prior to use. If the QC material is compromised, then the QC results obtained when using it are not a valid assessment of your test.

By performing a new control lot verification (sometimes called lot-to-lot QC testing) prior to the expiration date of the previous lot of controls, you can detect any degradation or contamination of your new lot prior to using it as your daily QC material.

• How to Verify a New Lot of Controls •

This process should take place several days before the control lot currently in use either expires or runs out. The testing should take place over several days, and be performed by several operators. The exact process to use is at the discretion of the Laboratory Director. An example follows:

1) Run daily QC on the current lot number and ensure that it is in the acceptable range.

2) Run all levels of the new lot of controls.

NOTE: The new lot should be run as a patient, or in a different QC file, if the instrument or LIS has that capacity. These results are not the day's official QC runs.

3) Record results (see the attached **QC Verification Log template).**

4) Repeat the above steps on at least 5 days, with different operators.

5) Compare the results of the new control with the manufacturer's expected control range, as stated in the package insert.

- If the results are **within the manufacturer's range**, the new QC lot is verified and is ready for use. The manufacturer ranges may be used as the new control ranges.
- Be sure to enter the new QC ranges into the instrument, if applicable, when you are ready to use the new lot.
- If the results fall **outside the manufacturer's range**, take corrective action to determine the issue.

Suggestions for corrective action include:

- Check that the correct instrument ranges are being used; some package inserts will list many ranges, for several instruments.
- Verify the status of the *current* lot number of controls. If there have been recent shifts or trends, the instrument may need calibration before proceeding.
- Confirm that all required calibrations and maintenance have been performed.
- Mix and rerun the controls.
- Repeat the testing with new vials of controls.
- Check the shipping information. If the controls were warm when received, contact the manufacturer for a new shipment.
- Notify the control manufacturer. Other labs may be having similar problems. They may be able to send a different lot number.
- Notify the Lab Director or Supervisor, and document all corrective actions.

6) The Laboratory Director or Technical Consultant/Supervisor must review and approve the study before the new QC lot can be put into use.

7) On the QC package insert, record the "in use" date and retain the insert and all documentation generated from the lot-to-lot verification for at least two years.

• How to Establish Acceptable Ranges for Unassayed Controls •

In some cases, QC material is unassayed; that is, the manufacturer does not provide any acceptable ranges for the controls. In most cases there will only be a target mean value listed for each applicable instrument. In the case of unassayed controls, each laboratory must establish their own QC ranges prior to use. This is a regulatory requirement and can be found under QC 9 in the COLA Accreditation manual.
As with assayed controls, this process should take place several days before the control lot currently in use either expires or runs out. The biggest difference with *unassayed* controls is that a laboratory will need to collect more data to analyze, in order to establish reasonable acceptable ranges. The testing should also take place over several days, and be performed by several operators. The exact process to use is at the discretion of the Laboratory Director. An example follows:

1) Run daily QC on the current lot number and ensure that it is in the acceptable range.

2) Run all levels of the new lot of controls.

NOTE: The new lot should be run as a patient, or in a different QC file, if the instrument or LIS has that capacity. These results are not the day's official QC runs.

3) Record results (use of a spreadsheet is recommended)

4) Repeat the above steps **at least 20 times**, over at least 5 days, with different operators. **A minimum of 20 data points** are required to achieve statistical significance.

5) Using the collected data, calculate the following:

- Mean
- Standard Deviation (SD)
- Coefficient of Variation (CV)

6) Evaluate your data: is the difference between the calculated mean and the expected manufacturer mean acceptable? A good target is having your mean fall within 1 SD of the manufacturer's mean. If troubleshooting is necessary, refer to the list of suggested corrective actions found on the previous page.

7) Compare the calculated CV to your previous lot's historic CV for each analyte and QC level. This is a calculation of precision.

- If historical data is unavailable (a new test or control material), then contact the QC manufacturer to obtain interlaboratory peer group data for the lot being evaluated.
- Review the cumulative peer group data if available to determine if the CV is acceptable.

8) Calculate a second SD based on the historic or peer group CV.

9) Establish control ranges for the new control lot using your mean and calculated SD.

- Determine the 2 SD ranges by multiplying the calculated SD by 2, then add and subtract this result from the mean.
- Determine the 3 SD control range by multiplying the calculated SD by 3, then add and subtract each result from the mean.

10) The Laboratory Director or Technical Consultant/Supervisor must review and approve the study before the new QC lot can be put into use.

11) On the QC package insert, record the "in use" date and retain the insert and all documentation generated from the lot-to-lot verification for at least two years.

12) Enroll in an interlaboratory peer group if available and submit control data monthly. Evaluate your data with the peer group monthly.

• References •

- Clinical Laboratory and Standards Institute (www.clsi.org)
  Statistical Quality Control for Quantitative Measurement Procedures – C24-A3
  940 West Valley Road, Suite 1400, Wayne, PA 19087
  Phone: (610) 688-0100

- COLA Criteria QC 8, QC 9 (www.cola.org)
  9881 Broken Land Parkway, Suite 200, Columbia, MD 21046
  Phone: (800) 981-9883

• Template Form •

New QC Lot Verification Worksheet: See pages 6 and 7

New QC Lot Verification Worksheet

Instrument: _____

Analyte: _____

Instructions:

1. Follow all manufacturer's instructions for the proper warm up and mixing procedures for your control material.
2. Run daily QC on the current (old) lot number of controls and ensure that they are the acceptable range. If QC fails, document corrective action as appropriate.
3. Run all levels of the new lot of controls one time. Record results.
4. Repeat the above steps on **at least 5 different days, with different operators if possible**.
5. Compare the results of the new control with the manufacturer's expected range for that control, as stated in the package insert. Indicate Pass/Fail for each result.
   - If the results obtained fall **within the manufacturer's range**, the new QC lot is verified and is ready for use. The manufacturer's stated QC ranges may be used as the new control ranges.

If the results fall **outside the manufacturer's range**, take corrective action to determine the issue, and repeat QC lot validation on a new worksheet.

Control Information		Expiration Date	Results	Manufacturer's Acceptable Range	Pass/Fail	Date Tested	Initials
Level	Lot Number						

Comments/Corrective Actions Taken:

_____

_____

_____

_____

_____

_____

_____

New Lot# Verified for Use? _____YES _____NO

Reviewed & Approved: _____ Date: _____

Title: _____