COLA Clinical Laboratory Accreditation

COLA Primers Accreditation

COLA PRIMER 50

Quality Control Basics

•Overview •

It is important that laboratories provide accurate and reliable laboratory results to clinicians. Quality Control (QC) is an essential component which is used to ensure that laboratory results are both precise and accurate. Quality Control consists of the procedures used to detect errors that occur due to test system failure, environmental conditions, and operator performance.

A successful Quality Control program includes several aspects such as written and approved QC plans, proper QC practices, appropriate QC documentation, and effective QC review.
Quality Control is required for qualitative and quantitative tests.

> **Qualitative assays** are those generally reported as presence or absence, positive or negative, reactive or non-reactive, or of graded reactivity (weakly or strongly reactive).
>
> **Quantitative assays** are those reported with a numerical value such as 10 mg/dl.

Quality Control measures are also required for items such as microscopic examinations. When applicable, Quality Control programs must also address items such as extraction phases, molecular amplification, stains, or titrations.

Controls are classified into external QC and internal QC.

> **External QC** is the testing of control material that is not built into the test system. The control material is sampled and tested by the test system in the same way a patient specimen is sampled and tested.
>
> **Internal QC** is built into the test system.

•Quality Control Plan •

A complete and effective Quality Control plan will adhere to CLIA requirements, COLA requirements, state requirements, and manufacturer requirements. Please keep in mind that the laboratory must adhere to whichever is the most stringent. Most non-waived testing requires a minimum of two levels of external QC each day of patient testing. Quality Control should also be performed after a complete change of reagents, after calibration, after major preventative maintenance is performed, as well as after replacement of any critical analyzer parts. Several specialties have QC requirements that vary from this standard.

For eligible test systems, an Individualized Quality Control Plan (IQCP) may be used by the laboratory to establish their own QC frequency as long as it minimally meets the requirements of the manufacturer. See COLA Primer 53 for details on IQCP. For waived testing, COLA requires laboratories adhere to manufacturer requirements.

Quality Control should be run in the same manner as patient samples. This includes who runs QC and how QC will be performed. For example QC should be performed by individuals that perform actual patient testing. Each of the testing personnel should participate in the performance of Quality Control.

Each laboratory should have a quality control plan that is used to monitor the complete analytic process for each test performed. This plan should define

- the number of controls to be run,
- the type of controls to be run,
- the frequency of Quality Control performance,
- expected ranges for control values,
- the established limits of acceptability,
- descriptions of corrective action to be performed for unacceptable QC,
- a process of review for all QC activities, and
- a means for ensuring documentation and storage of all Quality Control records.

The number, type, and frequency of controls should minimally meet CLIA, COLA, state, and manufacturer requirements. Again, keeping in mind that **if** there are different requirements then the laboratory must adhere to the most stringent. Several test systems or kit tests may additionally include Quality Control materials that may be utilized by the lab.

•Expected QC Results •

Expected ranges for Quality Control will be either established by the manufacturer or established by the laboratory. Limits of acceptability are the guidelines that the laboratory has implemented to determine if QC is within acceptable limits.

New lot numbers of Quality Control materials must be verified by repetitive testing prior to use. This is accomplished by performing parallel testing of QC. The new lot number of control materials should be run for at least five different days along with the current lot of Quality Control. This is not applicable to test systems where the new controls, standards, and reagents come packaged together as a unit to be used together with no interchanging of materials among kits or lot numbers.

Controls may either be assayed or un-assayed.

> **Assayed** controls have ranges provided for the particular analyte on the specified analyzer. These are provided by the manufacturer of the control material. Please keep in mind that the ranges for many assayed controls are to be used as guidelines and may indicate that each lab should establish their own QC ranges.
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> **Un-assayed** controls do not provide ranges for the laboratories. In the case of un-assayed controls, each laboratory must establish their own QC ranges prior to use. Mean and standard deviation should not be established with less than 20 values.

Mean- The mean is defined as the average result. It is determined by adding all results and then dividing by the number of results used.

Standard Deviation (SD) - The standard deviation is a statistic that tells you how tightly all the various values are clustered around the mean in a set of data. It measures how spread out the values in a data set are. More precisely, it is a measure of the average difference between the values of the data in the set.

If the data points are all similar then the standard deviation will be low. If the data points are highly variable, then the standard variation is higher. Most labs use a 2 standard of deviation from the mean to establish QC ranges. 2 SD means that 95 percent of values should be within acceptable limits under normal conditions. In other words, one in 20 results will be out of range due to normal random error.

Example: Mean of 124mg/dl. 1 SD of 9. 2 SD of 18. QC range of 106-142 mg/dl.

• QC Review and Corrective Action •

Each lab must have a procedure for review of Quality Control. This should include daily review of QC to ensure that QC is acceptable prior to reporting patient results. There should also be a process indicating that QC reviews will be performed and documented every five to seven data points as well as monthly. QC reviews should be used to identify shifts, trends, random QC issues, and performance and documentation of corrective action.

For each quantitative test that is performed, the lab should either plot QC on a Levey-Jennings Chart or similar graph. QC graphs generally will indicate the date on the horizontal axis, the mean and SD along the vertical axis, and the QC data points will be plotted on the graph. Alternatively, the laboratory may calculate statistical parameters.

Shift- a shift is an abrupt change in the mean of the control. Some causes of a shift in QC can be related to new reagents, new controls, change in lot number of controls, recent calibration, major instrument maintenance, or various instrument issues.

Trend- a trend is a gradual change in Quality Control. Some causes of trends in QC can be related to deterioration of reagents or QC, contamination of reagents or QC, a drifting calibration, or deterioration of instrument parts such as tubing, pumps, or lamps.

A policy must be established for corrective action when controls are outside of acceptable limits.

The laboratory should have a step by step procedure indicating how corrective action will be performed and documented. It is a common misconception that just repeating controls until the result is in range is acceptable corrective action. Repeating the testing with a new bottle of control material is acceptable, but if the control result is still unacceptable then other corrective action should be taken, such as calibration and/or instrument maintenance.

•Documentation •

Immunohematology Quality Control records must be maintained for ten years. IQCP and associated risk assessments must be held for the period of time IQCP is implemented plus an additional two years. All other QC documentation must be maintained by the laboratory for a minimum of two years.

Please keep in mind that some states may have more stringent record retention requirements. If those requirements exceed those mentioned above than the lab must retain documentation for the longer period of time. Record keeping should include but not be limited to:

- lot number and expiration date of controls,
- expected ranges (mean and SD) of control materials,
- QC package inserts,
- QC values that have been obtained by running QC materials,
- identification of the testing personnel,
- corrective action,
- verification of new lots of QC,
- establishment of QC ranges,
- documentation of QC reviews,
- statistical data or charts such as Levey-Jennings (L-J) charts or QC graphs.

A robust Quality Control program with effective reviews is essential to the laboratory. This will provide early detection of instrument, reagent, control, or operator issues. Adherence to the QC guidelines listed above will be effective in producing reliable patient results.