QUALITY SYSTEMS: ANALYTIC PHASE CONTROL PROCEDURES

Introduction to Quality Systems

CLIA Facts 14: General Laboratory Practices contains an introduction to the quality systems concept. This fact sheet will discuss a component of the analytic phase of testing--control procedures.

Analytic Phase

The anayltic phase includes the resources used and the processes that occur during laboratory testing. These resources and processes are:

- Procedure manual
- Test systems, equipment, instruments, reagents, materials, and supplies
- Establishment and verification of performance specifications
- Calibration and calibration verification procedures
- Maintenance and function checks
- Test records
- Comparison of test results
- Corrective actions
- Control procedures (quality control)

The analytic phase is divided into five fact sheets. One of the most important processes of analytic systems is control procedures (quality control). The general control requirements that apply to all specialties are given here, but there are additional requirements for each testing specialty. These specialty requirements are addressed in separate fact sheets for each testing specialty.

Control Procedures

For each test system, your laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process. You must establish the number, type, and frequency of control materials to be tested.

Your control procedures must detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. They must also, over time, monitor for changes in test system performance, environmental conditions, and variance in operator performance.

Because electronic and built-in procedural controls likely cannot detect all these conditions, they may no longer be sufficient as the sole source of QC. The laboratory will need to test external controls, unless they conduct and document a study that qualifies alternative types of controls as an equivalent QC process.

Your laboratory must:

- Perform control procedures as defined in this section, unless there are additional specialty and subspecialty requirements.
- For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by your laboratory when they meet or exceed the requirements given below.
- At least once each day patient specimens are tested or examined:
  - Each quantitative procedure requires two controls of different concentrations
  - Each qualitative procedure requires a negative and positive control
  - Test procedures producing graded or titered results require a negative control and a control with graded or titered reactivity
  - Each test system that has an extraction phase requires two controls, including one that is capable of detecting errors in the extraction process
  - Each molecular amplification procedure requires two controls and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition
- Perform required control testing before resuming patient testing when a complete change of reagents is introduced; major preventive mainte-

nance is performed; or any critical part that may influence test performance is replaced.

- Over time, rotate control testing among all operators who perform the test.
- Test controls in the same manner as patient specimens.
- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.
- Be sure to establish or verify the criteria for acceptability of all control materials.
  - When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.
  - Your laboratory may use the stated value of a commercially assayed control material provided the stated value is for the method/instrumentation combination used by your laboratory and is verified by your laboratory.
  - Over time, your laboratory must establish statistical parameters for unassayed control materials through concurrent testing of assayed control materials.
- For thin layer chromatography:
  - Spot each plate or card with a calibrator containing all known substances or drug groups which are identified by thin layer chromatography and reported by your laboratory
  - Include at least one control on each plate or card which must be processed through each step of patient testing, including extraction processes
- For each electrophoretic procedure, include at least one control containing the substances being identified or measured, concurrent with patient specimens.

For reagent, media, and supply checks, your laboratory must do the following:

- Check each batch (when prepared in-house); each lot number (when commercially-prepared); and each shipment of reagents, disks, stains, antisera, and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.
- Each day of use, test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included.
- Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.
- Before, or concurrent with the initial use:
  - Check each batch of media for sterility if sterility is required for testing
  - Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response
  - Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer
- Follow the manufacturer's instructions for using reagents, media, and supplies and be responsible for results.

Results of control materials must meet your laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

You must document all control procedures performed. If control materials are not available, your laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

Quality Assessment of the Analytic Phase

Your laboratory must establish and follow written policies and procedures to actively monitor, assess, and correct problems identified in the analytic phase. Quality assessment of control procedures must include:

- Reviewing the effectiveness of corrective actions taken to resolve problems
- Revising appropriate policies and procedures to prevent problems from recurring
- Discussing the reviews with appropriate staff
- Documenting all quality assessment activities

Resources

- View the current laboratory requirements of Part 493, including the relevant Subpart K, at www.phppo.cdc.gov/clia/regs/toc.aspx
- Appendix C of the State Operations Manual (CMS Pub. 7) can be viewed online at: www.cms.hhs.gov/clia/03_interpretive_guidelines_for_laboratories.asp. (This document is the CMS Surveyor Procedures and Interpretive Guidelines. The Equivalent Quality Control Procedures mentioned in the regulations can be found under D-tag D5445 in this document.)