QUALITY SYSTEMS: ANALYTIC PHASE
COMPARISON OF TEST RESULTS & CORRECTIVE ACTIONS

Introduction to Quality Systems

CLIA Facts 14: General Laboratory Practices contains an introduction to the quality systems concept. This fact sheet will discuss two components of the analytic phase of testing--comparison of test results and corrective actions.

Analytic Phase

The analytic 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. Specialty-specific control procedures (quality control) are addressed in additional separate fact sheets for each testing specialty.

Let's continue with the next two components of the analytic phase:

- Comparison of test results
- Corrective actions

Comparison of Test Results

If your laboratory performs the same test using different methods or instruments, or performs the same test at multiple testing sites, then you must have a system that evaluates and defines the relationship between test results using the different methods, instruments, or testing sites twice a year. You must document all test result comparison activities.

Your laboratory must have a system to identify and evaluate patient test results that appear inconsistent with the following relevant criteria:

1. Patient age
2. Sex
3. Diagnosis or pertinent clinical data
4. Distribution of patient test results
5. Relationship with other test parameters

Corrective Actions

Corrective action policies and procedures must be available and followed to maintain your laboratory's ability to test patient specimens in a manner that ensures accurate and reliable patient test results and reports. You must document all corrective actions taken, including actions taken when any of the following occur:

1. Test systems do not meet your laboratory's verified or established performance specifications, including but not limited to:
    - Equipment or methods that perform outside of established performance specifications
    - Patient test values that are outside of your laboratory's reportable range of test results for the test system
    - Reference intervals (normal values) for a test procedure that are inappropriate for your laboratory's patient population.
2. Results of control and/or calibration materials fail to meet your laboratory's established criteria for acceptability. You must evaluate all patient test results obtained in the unacceptable test run, and since the last acceptable test run, to determine if patient test results have been adversely affected.
3. The criteria for proper storage of reagents and specimens are not met.

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. This quality assessment 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.)

CORRECTIVE ACTION POLICIES AND PROCEDURES MUST BE AVAILABLE AND FOLLOWED TO MAINTAIN YOUR LABORATORY'S ABILITY TO TEST PATIENT SPECIMENS IN A MANNER THAT ENSURES ACCURATE AND RELIABLE PATIENT TEST RESULTS AND REPORTS.