June 2004

Texas Association for Clinical Laboratory Science

TACLS News

A Message from the President

Christie Thompson, Ed.D.,TACLS President

Summer is here! We live on Mustang Island and the summer vacationers have arrived. Summer is a time for families, the beach and a break from school. May and June also means graduation and, for those graduates, job hunting. While some college graduates may not find employment or will only find employment after a prolonged search, graduates from clinical laboratory science programs will find many available positions. Most graduating clinical laboratory science students will have multiple job offers and can be selective in their work situation. Hospital officials have reported a vacancy rate of 10 percent among laboratory technologists and they indicated more difficulty in recruiting these same professionals than two years ago.

The Bureau of Labor Statistics projects that in the period 2000-2010, a total of 120,000 positions in clinical laboratory science will be needed in the form of creating 80,000 new jobs and filling 40,000 existing vacancies. Of the 12,000 openings per year, academic institutions are producing only 4,200 graduates annually. Since 70 percent of medical decisions are based on the results of laboratory tests, the future shortage of clinical laboratory science professionals has serious ramifications for quality health care. ASCLS and several other laboratory organizations started have been working together to address the growing crisis in clinical laboratory personnel, but national organizations cannot solve this problem. Individual members must implement and support recruitment efforts.

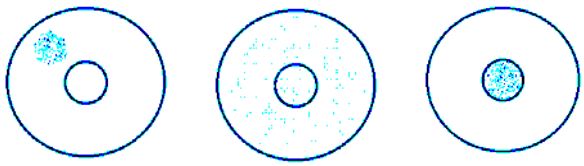
What can you do? Recruitment materials are available from several sources, including ASCLS and TACLS. Contact local high schools and junior high schools and volunteer to talk with science students about the clinical laboratory. Talk with local civic organizations, politicians and community leaders or contact local news organizations. The clinical laboratory is an exciting and dynamic profession with great potential. Share the excitement.

Final CLIA Rules on Quality Control
Quality Control – Why Is It Important?

Vicki Freeman, Ph.D., MT(ASCP)

Quality control (QC) is the backbone of all laboratory tests. QC is something that is learned from day one in medical technology education and is performed whenever patient results are reported. In the "olden" days, quality control was performed with every test run and verified by plotting on big QC charts that hung on the walls in each section of the laboratory. Only if the QC results fell within 2 standard deviations did patient results get reported. However, increased reliance on automation and concern about the costs of laboratory testing has challenged these basic quality control rules. Westgard, the guru of quality control, established the multirule QC standards in1981 (http://www.westgard.com/mltirul3.htm). Over the last 2 decades, the frequency of quality control was changed from every run to once per shift. New CLIA regulations are suggesting that these rules might be relaxed even more. This article will review the purpose of QC and discuss the newly published Clinical Laboratory Improvement Amendments (CLIA) rules on QC.

The purpose of QC is to assure the reliability of patient data obtained from a procedure and to monitor variables that can alter data. Properly performed QC can measure the *precision* and the *accuracy*. These two combine to measure the reliability of test results or the ability to maintain both precision and accuracy of the test. *Precision* is the reproducibility of the result while *accuracy* is the closeness of the measured result to the true value. An analogy to a bulls-eye can be drawn to QC. In the precision model, the results are all close together, but not near the center of the bulls-eye. The accuracy model shows the test results all within the larger circle, but not close together. Finally, in the reliability model the test results are both close together and within the center of the smaller circle, indicating the consistency of the results.

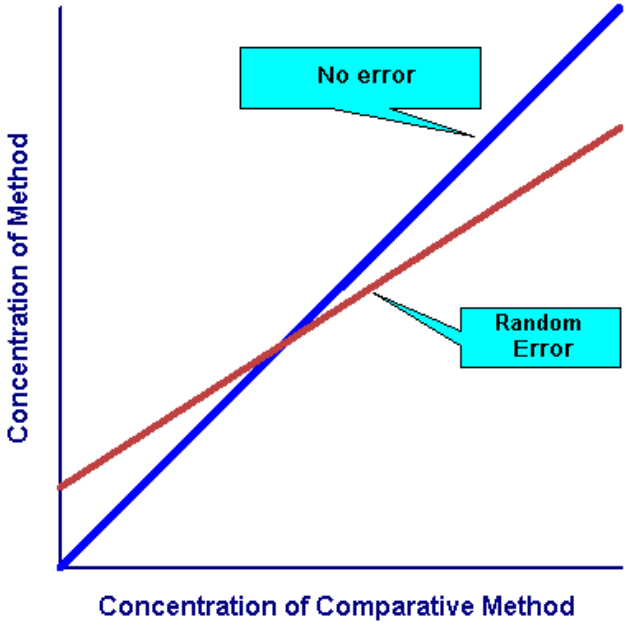


Precision Accuracy Reliability

Precision and accuracy basically measure two types of errors that can occur, *random* and *systematic*. The total error (TE) of a test is the sum of the random (RE) and the systematic error (SE) and represents the sum of the variability of the measurement process (imprecision) and the shift from a true value (inaccuracy) (TE = RE + SE).

Random errors are those errors that occur unpredictably due to factors such as instability in instruments, measurement, temperature or reagents or imprecision in pipetting. This type of error results in imprecision and an increase causes test results to be more variable. This variability can be both positive and negative.

Systematic errors are errors that occur in one direction only, increasing or decreasing results by the same amount. This type of error is due to factors such as erroneous values for standards, incomplete calibration of shifts in reagent baseline and results in inaccuracy of a test result. An increase in systematic error causes test results to be shifted away from the true value. The shift can be positive or negative and can be either proportional or constant errors.



Random Error

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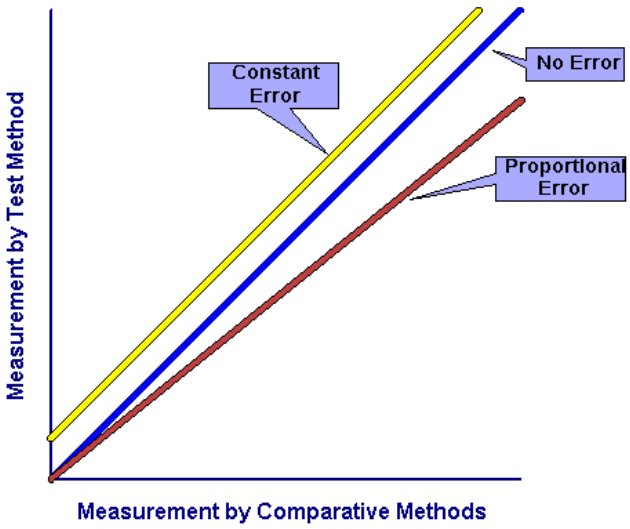
Systematic Error



The Final CLIA QC Requirements

The final CLIA rules that were published on January 24, 2003, and became effective April 24, 2003, outlined new QC requirements (for entire document, see http://www.access.gpo.gov/nara/cfr/waisidx_03/42cfr493_03.html). The bottom line in these rules is that "*for each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process*" (http://www.cms.hhs.gov/clia/apcsubk1.pdf D5441 ß493.1256, page 38).

A test system is defined by CLIA as the instructions and all of the instrumentation, equipment, reagents, and/or supplies needed to perform an assay or examination and generate test results. A few guidelines were established in the requirements. These include: 1) the control material must detect errors in the entire testing process and must also monitor the quality of the results provided by the test system, 2) the material may be supplied by the test system manufacturer or another source, but must be tested in the same manner as patient samples, and 3) the control testing must be rotated among all operators who perform the testing.

The rule leaves it up to the laboratory to establish the number, type, and frequency of testing control materials, but states that the lab must verify the manufacturer's published performance specifications or establish new ones itself (this will be discussed in a subsequent article. In addition, the rule reduced the required frequency of testing control materials from ''each run'' to ''each day of testing'' unless the manufacturer's instructions for control testing meet or exceed this requirement or the laboratory establishes an "*equivalent"* QC.

It is important to note the CLIA requires that *"The control procedures must monitor the complete analytical process in order to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance" (*http://www.cms.hhs.gov/clia/apcsubk1.pdf D5441 ß493.1256, Interpretive Guidelines ß493.1256(a)-(c)**,** page 38*)*. Additionally, the procedures must monitor over time the *accuracy* and *precision* of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance (for example, different operators and same operator variations in specimen handling and testing).

The Bottom Line for QC: Laboratories must analyze two control materials of different concentrations at least every day or 24 hour period unless CMS approves a procedure that provides equivalent quality testing. For each quantitative procedure the rule retained the former requirement of two control materials of different concentrations analyzed at least once each day that patient specimens are assayed or examined. Additionally, the new rule retained the positive and negative control requirements for qualitative procedures and the negative control and the control of graded or titered reactivity for test procedures producing graded or titered results.

Does "Equivalent" QC necessarily mean "reduced" QC?

What is Equivalent QC (or EqQC)? According to the CLIA rules, EqQC allows a laboratory to reduce QC from the minimum requirement of testing 2 controls per day to testing only 2 controls per week or only 2 controls per month. But this cannot be done without some work on the laboratory's part. To establish equivalency a laboratory must analyze 2 external controls per day for a period of 10 to 60 (depending on the type of system – discussed below) consecutive days to evaluate equivalent QC. If the internal and external control results are acceptable during this entire period of testing, the laboratory may reduce the external control testing interval again based on the system type.

Tests systems eligible for EqQC include those systems with internal or procedural controls that monitor all analytic testing components. For these systems, the QC testing required is based on ***10*** days of testing for test systems with internal or procedural controls that monitor all analytic testing components, QC can be reduced to ***one time per month***. For test systems with internal or procedural controls that monitor a ***portion*** of the analytic testing components, ***30*** days of testing without any QC problems will allow QC reduction to ***once a week***. For test systems with no internal or procedural controls, it takes ***60*** days of testing without any QC problems to change from daily to ***weekly*** QC.

Certain tests such as tests with an extraction phase, molecular amplification procedures, thin layer

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chromatography, electrophoretic procedures and specialty and subspecialty tests that have specific requirements are not eligible for EqQC. Specialties and Subspecialties tests include: 1) decreased frequency of QC testing for bacteriology and mycology reagent checks, 2) decreased frequency of QC testing for general immunology and syphilis serology to daily testing from concurrent with patient testing, and 3) decreased frequency for hematology QC testing to each day of use from each 8 hours of operation, 4) increased the frequency of QC testing for the subspecialty of mycobacteriology by adding a requirement for testing negative controls to check stains and reagents and increasing the frequency for checking fluorochrome and acid fast stains.

Where does this leave us?

According to the Centers for Medicare & Medicaid Services (CMS), "Since the purpose of control testing is to detect immediate errors and monitor performance over time, increasing the interval between control testing (i.e. weekly, or monthly) will require a more extensive evaluation of patient test results when control failure occurs (Section *493.1282*). The [laboratory] director must consider the laboratory's clinical and legal responsibility for providing accurate and reliable patient test results versus the cost implications of reducing the quality control testing frequency". (http://www.cms.hhs.gov/clia/apcsubk1.pdf, page 40)

According to Westgard

"No laboratory is required to implement "equivalent QC" and we should not adopt this fatally flawed practice!" (http://www.westgard.com/cliafinalrule7.htm) I leave it up to you to make the final determination on what we, as laboratorians, believe is the standard by which we should practice. Do we follow the federal government's determination of what constitutes good laboratory practice or that of the equipment manufacturers? Or do we proactively establish our own standards based on what we know about precision, accuracy, random and systematic errors?

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Next month: Establishing Performance Specifications

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