

## CAP/CLIA Regulatory Updates

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Laboratories must review and perform method validation measures on all quantitative tests. These testing requirements include accuracy, precision, analytic sensitivity [lower level of detection], analytic specificity [note interferences], the reportable range and the reference range. If a test is Food and Drug Administration (FDA) cleared/approved, these parameters must be verified with validation signed by the Medical Director of that discipline or of the laboratory. Analytical sensitivity, specificity and in some age groups, reference ranges can be obtained from the manufacturer. For testing that is not FDA approved, all 6 of the testing requirements must be established “in-house.” This information is retained by the laboratory for the duration of that instrument plus 2 years, 10 years, or indefinitely depending on which agency’s regulations apply. To establish a plan of action to satisfy the performance guidelines, the Clinical and Laboratory Standards Institute (CLSI) provides reference guidelines. For instance, CLSI document C28-A2 provides direction in determining reference ranges while EP5 gives guidance for evaluation of precision. When doing test validations, the matrix (e.g. specimen type of the testing fluid) also must be considered. Some tests must be run on several matrixes and all of them must be verified or established depending on FDA approval of the exact method used.

Once testing has been validated, College of American Pathologist (CAP) & Clinical Laboratory Improvement Amendment (CLIA) require proficiency testing (PT) be performed every six months. CLIA does not require that PT be done on waived testing although highly recommended. CLIA requires that PT be performed on all regulated analytes posted on its website.

Competency of personnel performing the test is required by both CLIA and CAP. In the first year a person works in the laboratory, competency assessment must be performed at 6 months and at 12 months, and annually thereafter. Specimen collection and critical result reporting were added to competency assessment criteria in 2007. This evaluation may be done by direct observational methods such as monitoring of testing records including, where applicable, critical results, review of test result worksheets, QC records, proficiency testing records, preventive maintenance records, evaluation of problem-solving skills and testing previously resulted assays. This monitoring is documented and kept in the appropriate personnel file or in another location designated for competency testing.

Personnel records are inspected thoroughly by both CLIA and CAP. CLIA personnel requirements can be found at <http://www.cms.gov/clia>. CAP requirements can be found in the CAP General checklist under “All Personnel”.

Critical results are required to be notified to the individual or entity requesting the test results. When critical results are obtained, notification of these results must be made and documented on the test report. This is a Joint Commission, CLIA and CAP requirement. Individual hospitals generally develop a critical test list.

CAP requires that computer systems transporting patient results are checked for accuracy across interfaces. Laboratory reports must also be retained for 2 years [GEN.20377] unless longer periods are required (e.g., surgical pathology and cytopathology reports and blood bank reports). CAP [GEN.41310] also requires that on corrected reports, both the original result and the corrected result be present and identified. Computerized calculations [GEN.43450] must be checked every 2 years or after the system is changed in any way that could affect calculations.

Another area of CAP checklist questions involves Direct To Consumer (DTC) testing. If the laboratory offers any DTC testing, CAP has a number of phase II standards in the 2009 checklist. A laboratory that offers DTC testing must send the result to the patient’s practitioner IF requested. The lab must give the patient contact information for a health care practitioner and the results must include an interpretation in lay terms. If the result is CRITICAL, the lab must contact the consumer with the results in a timely manner. These results must be retained for 10 years.

### References

*CAP Checklist Updates*, 2009 LAP Audioconference Series sponsored by The Commission of Laboratory Accreditation of the College of American Pathologists (CAP). Stephen J. Sarewitz, MD, FCAP. Recording can be found at [www.cap.org](http://www.cap.org)