

CLIA Corner

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In This Issue of the CLIA Corner we address:

- **CLIA Frequently Asked Questions**

Q: Is proficiency testing required for computer (electronic) crossmatches?

A: No; the computer (electronic) crossmatch is a process of ensuring that a unit of blood is compatible with a specified recipient by means of electronically matching patient pre-transfusion test results (ABO/Rh, etc.) with information about the donor unit that is stored in the laboratory information system (LIS). It is not strictly considered a “test” under CLIA, and therefore proficiency testing is not required. However, the laboratory must have policies and procedures in place for performing computer (electronic) crossmatches and also systems in place to ensure that the LIS has been validated and functions as intended.

Q: For donor red blood cell (RBC) units or products, when is the laboratory required to confirm the Rh type?

A: As part of the procedures to demonstrate incompatibility between the donor’s cell type and the recipient’s serum or plasma type, the laboratory must confirm the ABO group of all RBC units and the Rh type of RBC units labeled as Rh negative prior to transfusion. Confirmatory testing for weak D is not required as part of the Rh type recheck.

Q: Does CLIA require annual review and approval of procedures by the laboratory director?

A: No; the CLIA regulation at D5407, 42 CFR §493.1251(d), states that “Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.” The Interpretive Guidelines at D5407 clarifies the following:

- *Annual review of procedures is not required;*
- *A coversheet may be used for the director to approve the manual; and*
- *All laboratory procedures including CDC and AFIP manuals, manufacturer’s operator manuals, and package inserts must reflect the director’s review and approval including any modifications to the procedure.*

Remember that all changes to a procedure must be approved, signed, and dated by the laboratory director. This responsibility **cannot be delegated** to anyone other than the laboratory director.

Q: Is the laboratory required to rotate proficiency testing (PT) samples among all testing personnel?

A: Yes; proficiency testing must be rotated among all testing personnel. There are a couple of different CLIA regulations that address the issue of rotating PT testing.

D2007, 42 CFR §493.801(b) states that *“The samples must be examined or tested with the laboratory’s regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory’s routine methods.”* All testing personnel documented on the CMS-209 Laboratory Personnel Report are required to perform proficiency testing in each specialty and subspecialty of patient testing that they are approved to perform. Generally there are only three proficiency testing events per year, so if the laboratory has more than three testing personnel it may rotate the additional personnel in subsequent years.

D6051, 42 CFR §493.1413(b)(8)(v) and D6125, 42 CFR §493.1451(b)(8)(v), states either the technical consultant or technical supervisor responsibilities include, *“Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include-- but are not limited to—the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.”*

One of the six CLIA competency criteria that must be addressed annually is the assessment of test performance. This can be accomplished by rotating PT samples among the testing personnel. A problem that frequently occurs is having too many testing personnel and not enough PT samples. The laboratory can meet this standard by having the testing personnel perform tests on previously tested patient specimens and/or by performing blind testing. Blind testing is where one person performs testing on a specimen and then other persons perform the same test on the same specimen, and their results are compared. Finally, the laboratory can rerun PT samples **AFTER** the results have been returned to the laboratory and perform a self-evaluation of the results.

Q: My lab has a Certificate of Accreditation (COA); who do I contact to change the laboratory director?

A: Recently, the Centers for Medicaid and Medicare Services (CMS) implemented a policy change in which laboratory accrediting organizations (AOs) (e.g. College of American Pathology, Joint Commission, COLA, etc.) are now responsible for making laboratory director changes for their respective accredited laboratories. Laboratories that currently have COAs must contact their respective AO for laboratory director changes. The AO is responsible for qualifying individuals as laboratory directors and updating the database. Laboratories applying for a COA must still send initial applications and laboratory director qualifications to their respective State Agency (SA) representatives who will qualify individuals as laboratory directors and enter the application into the CMS database.

Laboratories that currently have COAs and wish to make any changes other than the laboratory director must still submit those changes to their respective SA representatives. The AO is only responsible for laboratory director changes.

References:

State Operations Manual; Appendix C – Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services; Rev. 166, 02-03-17.