Q&A column

Editor: Frederick L. Kiechle, MD, PhD

Submit your pathology-related question for reply by appropriate medical consultants. CAP TODAY will make every effort to answer all relevant questions. However, those questions that are not of general interest may not receive a reply. For your question to be considered, you must include your name and address; this information will be omitted if your question is published in CAP TODAY.

Q. I am a nurse in a cardiac cath lab that performs point-of-care testing, including for activated clotting time. At my hospital, the POC testing coordinator only allows other cath lab staff, usually nurses, to use POC testing equipment if they have a copy of their diploma. Can staff who have proof of licensure (such as from the American Registry of Radiologic Technologists) but do not have a copy of their diploma be authorized to use POC testing equipment?

A.Laboratory and nonlaboratory testing personnel (nurses, respiratory therapists, radiologic technologists, and medical assistants) must meet the qualifications appropriate for the complexity of testing performed. Nonlaboratory personnel licensure is not acceptable documentation to demonstrate compliance with CLIA regulations for laboratory testing. All nonlaboratory personnel performing nonwaived POC testing must have proof of academic achievement, such as a copy of their diploma, transcript, primary source verification report confirming credentials, or equivalency evaluation from a nationally recognized organization for personnel trained outside of the United States.

Per CAP laboratory general checklist requirement GEN.54750 Nonwaived Testing Personnel Qualifications, personnel performing moderate-complexity testing, including nonlaboratory personnel, must have a minimum of one of the following:

- an MD or DO degree with a current medical license.
- a doctoral degree in clinical laboratory science or in a chemical, physical, or biological science.
- a master's or bachelor's degree in medical technology, clinical laboratory science, or in a chemical, physical, or biological science.
- an associate's degree in a chemical, physical, or biological science or in medical laboratory technology.
- a high school diploma or equivalent and record of having successfully completed U.S. military training of 50 or more weeks and served as a medical laboratory specialist.
- a high school diploma or equivalent and a record of appropriate training and experience, as defined in CLIA regulation 42 CFR §493.1423, Testing Personnel Qualifications.

The laboratory must have records demonstrating that personnel meet minimum qualifications before authorizing

them to perform patient testing.

For more information on what must be included in personnel records, refer to laboratory general checklist requirement GEN.54400 Personnel Records.

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Q. I recently joined a hospital laboratory that verifies reagents lot to lot with patient samples using a percentage difference of 10 for all parameters. The hospital lab where I previously worked used a CLIA allowable-error percentage. Is 10 percent allowable error acceptable for reagent lot-to-lot verification for all parameters?

A. Performing lot-to-lot verification is important for detecting significant changes in test performance between reagent lots. There are no universally accepted criteria for lot-to-lot verification. Each laboratory director should define the magnitude of the difference in patient results that may warrant a change in clinical management. Using ±10 percent as a universal criterion may cause a lab to be more or less stringent than is appropriate for a specific test.

The Clinical and Laboratory Standards Institute's EP26-A guideline provides a protocol for lot-to-lot verification. The protocol describes how to define a clinically significant difference and set appropriate rejection limits for patient results when changing reagent lots. Additionally, there are several examples in the literature in which labs describe their acceptance criteria for lot-to-lot verification and how the criteria were established.

The CLSI guidelines and literature references are helpful resources when deciding on appropriate lot-to-lot acceptability criteria for an individual laboratory.

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Thompson S, Chesher D. Lot-to-lot variation. *Clin Biochem Rev*. 2018;39(2):51–60.

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