OneLab™
A Unified Response to Training Needs

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations

FREQUENTLY ASKED QUESTIONS

General Proficiency and Testing Resources

Where can I find resources for general proficiency testing questions?

The Centers for Medicare & Medicaid Services (CMS) offers two CLIA resources for laboratories: Interpretive Guidelines for Laboratories | CMS and CLIA Proficiency Testing and PT Referral booklet (cms.gov)

What if there is no approved proficiency testing program for an analyte/test that my laboratory tests?

If there are no approved providers offering proficiency testing for your analyte/test, then laboratories are required to assess accuracy twice a year. Laboratories commonly refer to this as an alternative proficiency testing assessment.

Where can I find the list of CMS-approved proficiency testing providers?

You can find the U.S. Department of Health and Human Services-approved Proficiency Testing Program Providers list on the CMS/CLIA website: CLIA Approved Proficiency Testing Programs

Grading

Did CLIA change the acceptance criteria for proficiency testing?

Yes. Find the updated criteria for all analytes/tests in Subpart I of the Proficiency Testing Final Rule at Federal Register: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance.

How should a laboratory handle proficiency testing failures?

The laboratory should follow their quality assessment policy to investigate proficiency testing failures. The laboratory should consider whether failures may have affected patient testing and results.

Mycology and Parasitology

What does "requires direct antigen testing" mean to proficiency testing programs in mycology and parasitology?

Starting in January 2025, requirements for annual proficiency testing programs must include specimens to directly detect bacterial, fungal, parasitic, and viral antigens. Some examples of antigen detection include Group A *Streptococcus* antigen, *Clostridioides difficile* antigen, Group B *Streptococcus* antigen, *Cryptococcus* antigen, *Giardia* and *Cryptosporidium* antigens, influenza antigen, and respiratory syncytial virus antigen.

Susceptibility

How did requirements change for antimicrobial susceptibility proficiency testing?

As published in the Proficiency Testing Final Rule that will be effective January 1, 2025, facilities must conduct antimicrobial susceptibility testing for the subspecialty of bacteriology. The proficiency testing program must provide at least two specimens for antimicrobial susceptibility testing per testing event. The laboratory must perform antimicrobial susceptibility testing on two proficiency testing specimens per event, regardless of the specimen source. CLIA previously required only one specimen per testing event.

Waived Testing and Provider-Performed Microscopy

If my laboratory only performs waived testing, are we required to perform proficiency testing?

If your facility is only performing waived tests under a Certificate of Waiver (CoW) or Certificate for Provider-Performed Microscopy (PPM), CLIA does not require proficiency testing for waived tests. While proficiency testing for waived testing is good laboratory practice, CLIA laws and regulations do not require this.

If your facility (regardless of the type of healthcare center) is performing nonwaived tests and holds a Certificate of Compliance (CoC) or Certificate of Accreditation (CoA), then your facility must perform proficiency testing for all the tests your facility completes.

When and Where

When do these proficiency testing changes go into effect and where can I find more information?

Laboratories must implement the Proficiency Testing Final Rule by January 1, 2025. Find more information about the changes in the Proficiency Testing Final Rule Fact Sheet and the CMS-3355-F Final Rule.

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