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CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

PROFICIENCY TESTING REGULATIONS RELATED TO ANALYTES AND ACCEPTABLE PERFORMANCE – A FINAL RULE (MICROBIOLOGY)

Introduction

The Clinical Laboratory Improvement Amendments (CLIA) have released new minimum performance specifications for Proficiency Testing (PT) in the form of a 'Final Rule' document, due to be implemented in July 2024. This final rule updates the PT regulations under CLIA 1988 to address changes in the requirements for existing analytes and novel technologies. This update also includes technical changes to PT regulations to bring them in line with the CLIA statute.

In 1988, US congress enacted CLIA 1988 to ensure the accuracy and reliability of testing in all laboratories that test human samples with the intention of providing information to aid in diagnosis, prevention and treatment of diseases, or the assessment of health in humans. While ground-breaking at the time, testing methodologies and technologies have evolved dramatically since these initial guidelines were published in 1992.

This final rule includes changes to definitions and procedures associated with PT relating to all laboratory specialities and several updates to existing regulations. The addition of many analytes to those regulated by CLIA and the changes in acceptable performance goals outlined in this update aim to improve laboratory testing proficiency across all laboratories and disciplines to improve patient outcomes and reduce the frequency of incorrect analysis, diagnosis, and treatment.

This guide details the major updates to PT regulations for microbiology.

Changes to Microbiology Proficiency Testing

Categories of Testing

"A system for categorising types of service should be maintained in the regulations to help laboratories determine what PT they need to perform and assist surveyors in monitoring PT performance and patient testing."

To this end, CLIA regulations have been updated to have categories more suitable to the subspeciality and specific requirements which should be included in annual PT. The table below details these updates:

Subspeciality	Categories for testing	Required annual inclusions
Bacteriology	Gram stain including bacterial morphology. Direct bacterial antigen detection. Bacterial toxin detection. Detection and identification of bacteria which includes either: detection of growth or no growth in culture media or identification of bacteria to the highest level that the laboratory reports results on patient specimens. Antimicrobial susceptibility testing on select bacteria.	Gram-negative bacilli. Gram-positive bacilli. Gram-negative cocci. Gram-positive cocci.
Mycobacteriology	Acid-fast stain. Detection and identification of mycobacteria which includes one of the following: detection of growth or no growth in culture media or identification of mycobacteria.	Mycobacterium tuberculosis complex and Mycobacterium other than tuberculosis (MOTT). If appropriate for the sample sources.
Mycology	Direct fungal antigen detection. Detection and identification of fungi and aerobic actinomycetes which includes one of the following: detection of growth or no growth in culture media or identification of fungi and aerobic actinomycetes.	Yeast or yeast-like organisms. Moulds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucoromycetes. Aerobic actinomycetes.
Parasitology	Parasite antigen detection. Detection and identification of parasites.	Intestinal parasites. Blood and tissue parasites. If appropriate for the sample source.
Virology	Detection and identification of viruses.	Respiratory viruses. Herpes viruses. Enterovirus. Intestinal viruses. If appropriate for the sample source.

These changes have been implemented with the aim to remove the broad range of services listed for each subspeciality and replace them with categories which are more applicable to these subspecialities and better reflect the current practices in microbiology.

Major Groups of Microbiology

This update includes the removal of specific example organisms for each subspeciality and the addition of a list of more general organisms. This aims to clarify that PT programmes can be flexible when selecting samples, particularly as new species are identified as clinically relevant. This comes following the finding by the Clinical Laboratory Improvement Advisory Committee (CLIAC) that some PT providers only chose organisms from this list of examples in their challenge samples.

Declaration of Patient Reporting Practices

"Laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens."

This addition is included to enhance consistency among PT programmes when grading samples and to address the issue of laboratories inappropriately deciding whether to participate in a PT event based on the reporting criteria rather than the programme itself.

Gram Stain Proficiency Testing

"PT results for gram stain should include both stain reaction and morphology."

This update has been included as it is important to know the bacterial morphology for accurate identification of specific groups of bacteria. Therefore, it is important that laboratories are assessed on their ability to do so.

Mixed Culture Requirement

"Lower the mixed culture requirement from 50% to 25% for PT challenges of both sample types (those that require laboratories to report only principal pathogen and those that require laboratories to report all organisms present)"

This update has been applied to better reflect real patient samples and is applicable to the subspecialities of bacteriology, mycobacteriology, and mycology but not parasitology or virology.

Antimicrobial Susceptibility Testing

"Required PT for antimicrobial susceptibility testing should be increased to two challenges per event for a total of six challenges per year in bacteriology."

This update was recommended by CLIAC and aims to provide better assessment of laboratory performance over time. The recommendation that each event should include a gram-positive and a gram-negative challenge has been withdrawn as this was considered to give too much information to the laboratories taking part in the programme and would introduce undesirable predictability to the PT programme.

Direct Antigen Testing

The current regulations require direct antigen testing for the subspecialities of bacteriology and virology and this has been retained. In addition, direct antigen testing is now required for mycology, parasitology, and bacterial toxin detection.

The evaluation criteria for bacteriology and parasitology have also been updated to include performance and scoring criteria that address direct antigen and toxin detection. The score for these challenges will now be calculated as follows:

$$\frac{\textit{Number of correct responses}}{\textit{Number of Samples}} \; \textit{X 100}$$

These updates have been implemented to better reflect the best practices of these microbiology subspecialities.

Conclusion

The final rule for CLIA 1988 has been introduced with the aim to improve the accuracy of laboratory testing and update the regulation to bring them in line with the CLIA statute. This guide details many of the updates in relation to this final rule but is not comprehensive. It is recommended that laboratories in the US, and those who are CAP or JC accredited, should carry out an analysis of their current PT/EQA provider and their programmes to ensure they will achieve the requirements necessary to comply with these new CLIA regulations.

The introduction of these updated regulations in July 2024 will help to validate and improve the accuracy of methodologies used in diagnosis, prevention and treatment of patients and reduce the frequency of errors in the laboratory which ultimately leads to incorrect or delayed diagnosis and treatment.

References

1. Becerra X. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance. Federal Register. 2022;87(131):41194-41242.

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