COLA

CLIA FACTS #26

PROFICIENCY TESTING INFORMATION

Proficiency Testing (PT) is an important aspect of a laboratory's overall assessment of quality. PT serves as an external check to verify the accuracy of a laboratory's test results by providing unknown specimens for analysis by the laboratory.

When all of the participating laboratories submit results to the PT program, the results are grouped, statistically analyzed, and reported back to the laboratories.

Regulated Analytes

You are required to participate in proficiency testing for all regulated analytes on your test menu. Your PT program catalog will indicate which analytes are regulated, or see *Fast Facts 10: CLIA Regulated Analytes*, available free on the COLA Web Site. Once enrolled, laboratories are mailed five proficiency testing samples (called challenges) for each regulated analyte. These shipments, called events, are sent three times a year (except for mycobacteriology and cytology) and must be completed and submitted within a specified time frame.

Unregulated Analytes

Twice a year, you are required to verify the accuracy of the remaining, non-waived unregulated analytes on your test menu. You may perform split specimen analysis or voluntarily participate in PT to meet this requirement.

Most PT programs offer two challenges twice a year to provide a cost-effective option for unregulated analytes. PT is not required in any form for waived tests, but voluntary participation in one of the two challenge programs is a great way to add an extra measure of quality.

Successful Performance

To meet the requirements of CLIA, laboratories must pass two consecutive, or two out of three consecutive testing events to achieve successful participation.

To pass, laboratories must receive a score of at least 80% for the specialties and subspecialties of Microbiology, Immunology, Chemistry, Hematology, and Immunohematology.

ABO/Rh and compatibility testing require 100% to pass. The CLIA regulations, section 493.855, specify detailed PT requirements for Pap Smear testing in the specialty of cytology.

Unsuccessful Performance

Unsuccessful PT performance is the failure of two consecutive or two out of three events for an analyte. The CLIA regulations require that a laboratory with unsuccessful PT performance must cease patient testing for the analyte, specialty, or subspecialty. Reinstatement by successful performance for two events is required before patient testing may resume.

Provided the laboratory does not pose immediate jeopardy to patients, does not have a history of repeated PT failures, and agrees to cooperate with CMS, the agency may decide not to impose a cease testing order. In this scenario, the state survey agency of CMS will work with the laboratory to review PT performance.

Working together, the laboratory and state agency will review unsuccessful performance and develop technical assistance or an educational process to ensure the laboratory corrects and documents the PT failures.

PT Documentation

It is important to maintain accurate records for each testing event and to retain that documentation for two years. Document the handling, preparation, processing, and examination of the PT specimens and document each step in the testing process.

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For information about COLA services or for technical inquiries, call our Information Resource Center at (800) 981-9883.

Testing PT Specimens

CLIA requires that laboratories test PT specimens in the same manner as patient specimens. This means that the same laboratory staff who routinely perform patient testing should test the PT specimens using routine test methods. No repeat testing and averaging of results!

Laboratories are prohibited from comparing their results with another laboratory (even another location of the same practice) prior to submitting the results and are prohibited from sending the PT specimens to a reference laboratory. If the system you use to test an analyte is inoperable when PT specimens arrive, then call the PT provider to request an exception for the event.

PT Review

The laboratory director should review PT data on a regular basis with the staff to address any failures and evaluate PT performance. Take corrective action to resolve any issues and document all steps taken. PT scores, data, and documentation should be initialed and dated to indicate a review took place.

The PT review must include a self-evaluation when a regulated analyte is not graded by the PT provider or when a score does not reflect the laboratory's actual performance.

These situations occur when:

- A 0% score is given because the laboratory did not participate in the event.
- A 0% score is given because the laboratory did not submit the results to the PT program on time.
- A 100% score is given because an analyte, specialty or subspecialty could not be graded due to lack of a peer group.
- A 100% score is given because an analyte, specialty or subspecialty could not be graded due to lack of consensus. There must be 80% agreement among participating laboratories for consensus, with the exception of Immunohematology. See the CLIA regulations for detailed consensus requirements for Immunohematology. If the PT provider can not reach consensus, everyone gets a "free pass."

It is important to understand how to read and interpret PT reports and summary data, especially when self-evaluation is required. The laboratory must determine if their results are within acceptable limits, or if corrective action is needed.