Escalation Process for Proficiency Testing (PT) Failures of CLIA-Regulated Analytes/Subspecialties/Specialties

DEFINITIONS

Event: An occurrence of PT. Regulations require participation in 3 events per year for each analyte/subspecialty/specialty (Mycobacteriology requires 2 events per year).

Unsatisfactory PT performance: Failure to attain at least 80% for a regulated analyte/subspecialty/specialty. Clerical errors or data omissions are considered unsatisfactory PT performance.

Unsuccessful PT performance: Failure to attain at least 80% for a regulated analyte/subspecialty/specialty for 2 consecutive or 2 out of 3 testing events (ABO, Rh, and Compatibility testing requires 100%). Unsuccessful PT performance and unsuccessful PT participation are interchangeable.

Repeat unsuccessful PT performance (Cease Testing): Unsatisfactory PT performance in 3 consecutive, 3 out of 4, or 2 sets of 2 out of 3 PT events identified for the same regulated analyte/subspecialty/specialty within 6 PT events.

CAP PT PERFORMANCE MONITORING

As mandated by the Clinical Laboratory Improvement Amendments (CLIA), PT monitoring is a process that continually looks for trends of unsatisfactory PT performance.

Unsatisfactory PT performance must be investigated and documentation of corrective action must be maintained by the laboratory for inspection purposes.

Unsuccessful PT performance requires the laboratory to complete and return a Proficiency Testing Compliance Notice (PTCN) response form to the CAP, documenting corrective action taken to prevent further PT failures.

Repeat unsuccessful PT performance requires that the laboratory cease patient/client testing for the regulated analyte/subspecialty/specialty for a period of 6 months.

CEASE TESTING REINSTATEMENT REQUIREMENTS

Laboratories with repeat unsuccessful PT performance for a regulated analyte/subspecialty/specialty will be required to cease patient/client testing for that test. Per CLIA, cease testing will be enforced for 6 months.

Before the laboratory can resume testing, it must:

* Determine the reason for the PT failures.
* Determine whether patient results were impacted by the PT failures, and take appropriate action if patient results were affected.
* Develop and implement a corrective action plan to prevent future PT failures.
* Perform 2 events of successful reinstatement PT.
* Submit to the CAP appropriate documentation such as:
  * Investigation report
  * Corrective action plan
  * Patient impact analysis
  * Retraining documentation
  * Evidence on how the laboratory will ensure patient/client results are not reported during the cease testing period
  * Observe the CLIA-mandated 6 month cease testing period

Performing patient/client testing during a cease testing period will result in an adverse action against the laboratory’s accreditation status.

Note: If the regulated test is performed in more than one area or by more than one method in a single CLIA/CAP number, the cease testing directive applies to all areas and methods performing the regulated test.

FOR MORE INFORMATION

Need assistance? Call 800-323-4040 ext. 6052 or 847-832-7000, or email PTCN@cap.org.

Visit cap.org/elAB Solutions Suite/CAP Accreditation Resources/Proficiency Testing Toolbox (Analyte Specific Troubleshooting Guides are available in the Toolbox)

Go to www.cms.gov/Regulations and Guidance/Clinical Laboratory Improvement Amendments (CLIA)