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2026

PolicySource™

Laboratory

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- Those items with a paper clip icon 📎 are not P&Ps themselves but supplementary materials or attachments for a particular P&P. Not every P&P has such attachments, but that does not prohibit someone using *PolicySource* to create their own ancillary materials for any of their own P&Ps.

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Proficiency Testing Policy

[Logo]	**TITLE** Proficiency Testing Policy		**IDENTIFICATION NUMBER**
ORGANIZATION(S)	**LEVEL** ☐ System ☐ Organization ☐ Division ☐ Department	**CATEGORY** ☐ Clinical ☐ Management ☐ Regulatory	**POSTING DATE** **EFFECTIVE DATE**
REVIEW CYCLE ☐ 1 year ☐ 2 years **LAST REVIEW DATE:**		**REPLACES** **TITLE:** Proficiency Testing Policy **EFFECTIVE DATE(S):**	

APPLICABILITY

This policy is applicable to laboratories and correlates to Joint Commission standards that require written documentation. *See* Applicability Grid for applicable services.

POLICY STATEMENT

The laboratory independently participates in a proficiency testing program for all regulated analytes.

PURPOSE

To establish a process for participating in a US Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program independent of other laboratories to ensure consistently high-quality laboratory services and comply with law and regulation.

SCOPE

Applies to all of the following specialties practiced at the laboratory (as applicable):

- Microbiology
- Diagnostic immunology
- Chemistry
- Hematology
- Immunohematology
    - ABO group typing
    - Rho(D) typing
    - Unexpected antibody detection
    - Compatibility testing
    - Antibody identification

Applies to all of the following subspecialties practiced at the laboratory (as applicable):

- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology
- Syphilis serology
- General immunology
- Routine chemistry
- Endocrinology

- Toxicology
- Cytology (gynecologic examinations only)

Applies to all regulated analytes and performed in the laboratory.

Applies to each test method used as the primary method under each CLIA '88 certificate for each regulated analyte. **Note:** Proficiency testing is not required for secondary analyzers, test systems, assays, or examinations.

Does not apply to waived tests unless the laboratory chooses to enroll waived tests in proficiency testing. If the laboratory does choose to enroll waived tests in proficiency testing, they must comply with all elements of this policy.

DEFINITIONS

Analyte – A chemical substance in a fluid or other specimen that is undergoing analysis.

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) – Federal legislation that created uniform federal standards for regulating laboratory testing. CLIA '88 unified the disparate federal and state standards regulating clinical laboratories and extended government oversight to all testing facilities, including physician offices.

Proficiency testing – A peer comparison program used by laboratories to assess reliability of tests performed. Samples whose precise content is unknown are periodically provided to laboratories for testing, and the results are compared with those of other laboratories that perform the same tests.

Unsuccessful proficiency test performance – Failure to achieve satisfactory performance for two consecutive testing events or two out of three events; or failure to identify the same antibody in two consecutive or two out of three consecutive testing events.

RESPONSIBILITIES

The laboratory director is responsible for maintaining and implementing this policy.

The laboratory director is responsible for the following:

- Ensuring that the laboratory successfully participates in an approved proficiency testing program for all regulated analytes and tests
- Notifying the US Department of Health and Human Services (HHS) of the program(s) in which it chooses to participate
- Signing attestations to document that proficiency testing samples are tested in the same manner as patient samples

Note: *These responsibilities may be delegated, in writing, to a qualified technical consultant (for moderate-complexity testing) or technical supervisor (for high-complexity testing).*

- Establishing a rotation system that allows all laboratory staff members who perform testing to participate in the proficiency testing program

Qualified laboratory staff is responsible for the following unless delegated, in writing, to a qualified technical consultant (for moderate-complexity testing) or technical supervisor (for high-complexity testing):

- Testing proficiency testing samples in the same manner as patient samples
- Signing attestations to document that proficiency testing samples are tested in the same manner as patient samples

PROCEDURES

The laboratory director or designee does the following:

1. Selects the proficiency testing program(s) to be used by the laboratory.
2. Ensures that the proficiency testing program(s) selected is approved by CMS.
3. Authorizes the selected proficiency testing program to release data required to determine the laboratory's compliance.
4. Ensures that the laboratory participates in the same proficiency testing program(s) for at least a full calendar year prior to selecting a different proficiency testing program(s), whenever possible.
5. Notifies CMS or The Joint Commission prior to changing its proficiency testing program(s) if this change occurs prior to a full calendar year of the program's use by the laboratory.
6. Assigns proficiency testing activities to appropriate laboratory staff when materials arrive. This assignment is based on the established rotation schedule.
7. Prohibits communication with other laboratories about proficiency testing samples prior to submission of data to the proficiency testing provider.
8. Prohibits proficiency testing samples from being sent to another laboratory for analysis, including all of the following analytes:
    - Regulated and nonregulated
    - Nonwaived and waived
9. Notifies CMS and The Joint Commission of proficiency testing samples received from another laboratory for testing.
10. Signs attestation statements indicating the proficiency testing samples were tested in the same manner as patient samples.
11. Makes proficiency testing results available to the public in accordance with law and regulation.
12. Conducts a documented review of all reported results of proficiency testing, including those in which no problems are identified.
13. Confirms that all proficiency testing results meet acceptability requirements established by law and regulation, including the following:
    - Participation in a proficiency testing event
    - Attaining a score of 100% for all of the following:
        - ABO group and Rho(D) typing
        - Compatibility testing
        - Unexpected antibody detection
    - Attaining a score of at least 80% for all other specialties, subspecialities, and tests
    - Returning proficiency testing results to the provider within the established time frame
    - Submitting all results on the proficiency testing form
14. Supplements proficiency testing results for events with fewer than 10 participants with one of the following:
    - Interlaboratory comparisons
    - Non-CMS approved proficiency testing provided by the instrument manufacturer
15. Identifies proficiency testing results that are unsuccessful for each specialty, subspecialty, analyte, or test, as defined in this policy and CLIA '88, Subpart H.
16. Investigates unacceptable, unsatisfactory, ungradable (non-consensus) and unsuccessful results for clerical, technical, and methodological issues.
17. Designs and implements corrective actions to address the identified issues.
18. Documents the investigation and corrective actions.

Qualified laboratory staff member does the following:

1. Opens proficiency testing materials immediately upon arrival at the laboratory.
2. Inspects the package and materials for signs of damage or other conditions that would indicate compromised integrity.
3. Stores the materials according to the instructions included by the proficiency testing provider.
4. Notifies the laboratory director of the following:
    - Arrival of the materials
    - Status of the materials

Qualified laboratory staff member assigned to conduct the proficiency testing activities does the following:

1. Performs proficiency testing according to the instructions provided by the proficiency testing provider.
2. Performs proficiency testing using the same primary method used for regular patient samples.
3. Tests proficiency testing samples along with the regular patient testing workload.
4. Tests proficiency testing samples the same number of times as regular patient samples.
5. Documents proficiency testing samples in the same manner as regular patient samples.
6. Avoids communication with other laboratories about proficiency testing samples prior to submission of data to the proficiency testing provider.
7. Stores any unused proficiency testing material for use by off rotation personnel.
   Note: *Any reexamination of proficiency testing material must wait until after the submission period has ended.*
8. Signs attestation statements indicating the proficiency testing samples were tested in the same manner as patient samples.
9. Provides the laboratory director or designee with the attestation statement for their signature.
10. Completes proficiency testing prior to the due date established by the proficiency testing provider.
11. Submits the proficiency testing results to the proficiency testing provider prior to the established due date.

For Gynecologic Preparations

Laboratory staff members who examine gynecologic preparations do the following:

1. Participate in a CMS-approved proficiency testing program.
2. Demonstrate satisfactory performance on an annual proficiency testing event.
   Note: *Satisfactory performance is a score of 90% or more on a 10-slide proficiency test.*
3. Participate in required retesting activities, if he or she fails the annual proficiency test (such as receiving a score of less than 90% on a 10-slide test).
   Note: *Unexcused absence from any retesting activities will result in test failure.*

The laboratory director or designee does the following:

1. Identifies staff members who fail the annual proficiency test.
2. Schedules a retesting event for the individual to occur within 45 days of receiving notification of failure.
3. Conducts a 10-slide retest for the individual to be performed within two hours.
4. Identifies whether the 10-slide retest results are acceptable (such as a score of no less than 90%).

If the individual fails the 10-slide retest

1. Arranges for the individual to receive remedial training and education that addresses the area of deficiency.
2. Ensures that all slides evaluated by the individual are reexamined until acceptable performance is confirmed.
3. Conducts a 20-slide retest for the individual, to be performed within four hours.
4. Identifies whether the 20-slide retest results are acceptable (such as a score of no less than 90%).

If the individual fails the 20-slide retest

1. Prohibits the individual from examining gynecologic slides until acceptable proficiency is confirmed.
2. Arranges for the individual to receive at least 35 hours of formal, documented continuing education on the examination of gynecologic preparations.
3. Conducts additional 20-slide retests until a score of at least 90% is achieved.
4. Allows the individual to resume examination of gynecologic preparations only when acceptable proficiency is confirmed and documented in a 20-slide retest.

Record Retention

Appropriate laboratory staff retains documentation of proficiency testing activities for at least two years, including the following details of each activity:

- Each proficiency testing result
- The following events for all samples:
  - Test handling
  - Preparation
  - Processing
  - Examination
  - Each step in the testing process and reporting of results
- Signed attestation statement(s) provided by the proficiency program
- Copy of the proficiency testing report forms used to record proficiency testing results
- Corrective or remedial actions taken

For cytology proficiency testing

- Confirmation of acceptable testing performance of individuals who examine gynecologic preparations

  OR
- Documentation of retesting and corrective action taken when these individuals fail an annual proficiency testing event

Alternate Proficiency Testing

For tests that do not require proficiency testing, or for which proficiency testing is unavailable, a qualified laboratory staff member does the following:

1. Performs an alternative assessment system to determine reliability of analytic testing performance. This system includes any of the following methods:
   - Sending five specimens to a CLIA ’88–certified reference laboratory for comparison at least once every six months
   - Using interlaboratory quality control results to evaluate the laboratory’s accuracy and reliability
   - Retesting random samples of microscopic tests from each relevant staff member (This is conducted by the technical supervisor.)
   - Performing duplicate testing by two different individuals
2. Conducts and documents verification testing at least every six months.

3. Investigates any instances where performance verification does not meet acceptability standards.
4. Designs and implements corrective actions to address performance verification deficiencies.
5. Documents the investigation and corrective action processes.

REFERENCES

Joint Commission Standard LD.04.05.07, EP 4. The laboratory director, technical consultant, and/or technical supervisor do the following:

- Ascertain that the laboratory is enrolled and successfully participates in an approved proficiency testing program that is relevant for each test performed
- Review quality control and proficiency testing data
- Require corrective action and documentation on unacceptable quality control and proficiency testing results
- Evaluate the test results that appear inconsistent with clinically relevant criteria
- Discuss with staff any issues that have been identified

Joint Commission Standard QSA.01.01.01. The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.

Joint Commission Standard QSA.01.02.01. The laboratory maintains records of its participation in a proficiency testing program.

Joint Commission Standard QSA.01.03.01. The laboratory has a process for handling and testing proficiency testing samples.

Joint Commission Standard QSA.01.04.01. The laboratory performs its proficiency testing independent of other laboratories.

Joint Commission Standard QSA.01.05.01, EP 1. The laboratory has written policies and procedures that include acceptability criteria to evaluate the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and regulated analytes for which compatible proficiency testing samples are not available.

Joint Commission Standard QSA.01.05.01, EP 2. The laboratory performs verification testing at least every six months. The verification is documented.

Joint Commission Standard QSA.01.05.01, EP 3. When performance verification is unacceptable, the laboratory performs an investigation of all potential causes, evidence of review, and corrective action sufficient to address and correct the issues identified in the investigation. These activities are documented.

Centers for Medicare & Medicaid Services (CMS). CLIA Approved Proficiency Testing Programs, 2024.

Public Health Service Act. Section 353(f)(3)(F). Proficiency Testing Program: Testing Results.

ATTACHMENTS

Corrective Actions Policy (included in *PolicySource*)
Staff Qualifications Policy
Test, Method, and Instrument Quality Verification Policy (included in *PolicySource*)

APPROVAL

NAME AND CREDENTIALS **TITLE**	**NAME AND CREDENTIALS** **TITLE**
SIGNATURE	**DATE**
SIGNATURE	**DATE**