



2024 PolicySourceTM Laboratory

Policy SourceTM

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ISBN: 978-1-63585-377-3

Published by Joint Commission Resources

Oakbrook Terrace, Illinois 60181 USA

<https://www.jcrinc.com>

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- There are no brand-new policies and procedures in this 2024 edition of *PolicySource*.
- Some items in the Table of Contents are indicated as “updated.” This means that these policies and procedures (P&Ps) have been updated since the previous edition of *PolicySource*. These changes reflect updates in the Joint Commission standards and elements of performance for laboratory accreditation.
Note: A number of P&Ps have been updated due to changes in terminology. These are noted in orange in the Table of Contents and as “Terminology changes” in the chapter grids.
- Those items with a paperclip 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 [Number]
ORGANIZATION(S) [Organization name]	LEVEL <input type="checkbox"/> System <input type="checkbox"/> Organization <input type="checkbox"/> Division <input type="checkbox"/> Department	CATEGORY <input type="checkbox"/> Clinical <input type="checkbox"/> Management <input type="checkbox"/> Regulatory	POSTING DATE [MM/DD/YYYY] EFFECTIVE DATE [MM/DD/YYYY]
REVIEW CYCLE <input type="checkbox"/> 1 year <input type="checkbox"/> 2 years LAST REVIEW DATE: [MM/DD/YYYY]		REPLACES TITLE: Proficiency Testing Policy EFFECTIVE DATE(S): [MM/DD/YYYY]	

POLICY STATEMENT

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

PURPOSE

To establish a process for participating in a 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
 - Routine hematology
 - Coagulation
- Immunochemistry
 - 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 tests used for nonwaived testing at the laboratory.

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.

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 relevant analytes and tests
- 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:

- 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 to be used by the laboratory.
2. Ensures that the proficiency testing program 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, whenever possible.
5. Notifies CMS or The Joint Commission prior to changing its proficiency testing program 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 a reference laboratory for additional testing or confirmation, even if this would be required for a comparable patient sample.

9. Signs attestation statements indicating the proficiency testing samples were tested in the same manner as patient samples.
10. Makes proficiency testing results available to the public in accordance with law and regulation.
11. Conducts a documented review of all reported results of proficiency testing, including those in which no problems are identified.
12. 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 ABO group and Rho(D) typing and compatibility testing
 - Attaining a score of at least 80% for all other specialties, subspecialties, and tests
 - Returning proficiency testing results to the provider within the established time frame
 - Submitting all results on the proficiency testing form
13. 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
14. Identifies proficiency testing results that are unacceptable, according to the following criteria:
 - Individual unacceptable results
 - Late submission of results
 - Nonparticipation in a proficiency testing event
 - Lack of consensus among all laboratories participating in the event
15. Investigates unacceptable results using the following methods, as applicable:
 - Auditing documents for clerical errors
 - Reviewing documents for technical issues
 - Identifying any potential issues with methodology
16. Designs and implements corrective actions to address the identified issues.
17. 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 his or her 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 does the following:

1. Retains documentation of proficiency testing activities for at least **five years***, including the following details of each activity:

- Each proficiency testing result
- Test handling
- Preparation
- Processing
- Examination
- Each step in the testing process
- Signed attestation statement(s)
- Copy of the proficiency testing report forms
- Corrective 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, 2021.

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 [Name and Credentials]	NAME AND CREDENTIALS [Name and Credentials]
TITLE [Title]	TITLE [Title]
SIGNATURE	DATE [MM/DD/YYYY]
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