The Joint Commission

# Prepublication Requirements

• Issued September 20, 2024 •

Joint Commission Requirement

## Revisions to the LAB program related to Proficiency Testing

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online *E-dition*®), accredited organizations and paid subscribers can also view them in the monthly periodical The *Joint Commission Perspectives*®. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

**Please note:** Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

**APPLICABLE TO THE LABORATORY ACCREDITATION PROGRAM**

**Effective January 1, 2025**

### Quality System Assessment for Nonwaived Testing (QSA) Chapter

**QSA.01.01.01**

The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.
Note: This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).

**Element(s) of Performance for QSA.01.01.01**

EP 5 For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.
Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following:
- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.
- Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing ~~and~~ compatibility testing
- Attaining a score of 100% for ABO group and Rho(D) typing ~~or~~ compatibility testing
- Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.
- Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.
Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer.
(See also QSA.01.02.01, EP 2)

**Revised EP 5 For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.**
**Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following:**
**- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.**
**- Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing, compatibility testing, and unexpected antibody detection**
**- Attaining a score of 100% for ABO group and Rho(D) typing, compatibility testing, and unexpected antibody detection**
**- Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.**
**- Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.**
**Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer.**
**(See also QSA.01.02.01, EP 2)**

**Revisions include**: Changing "typing and compatibility testing" to "typing, compatibility testing, and unexpected anitbody detection" in the second and third bullets

**New EP 9** **The laboratory reports proficiency testing results for microbiology organism identification to the highest level that it reports results on patient specimens.**

## QSA.01.04.01

The laboratory performs its proficiency testing independent of other laboratories.

**Element(s) of Performance for QSA.01.04.01**

EP 1 The laboratory does not send the proficiency testing samples to another laboratory for analysis. (See also APR.01.02.01, EP 1)

**Revised EP 1** **The laboratory does not send the proficiency testing samples to another laboratory for analysis. <u>This applies to all proficiency testing samples, including regulated, nonregulated, and all nonwaived and waived analytes.</u>**
**<u>Note: Waived tests do not require proficiency testing (PT). If a laboratory chooses to enroll waived tests in PT, they must comply with all PT requirements, including the ban on improper PT referral.</u>**
**(See also APR.01.02.01, EP 1)**

**Revisions include**: Adding "This applies to all proficiency testing samples, including regulated, nonregulated, and all nonwaived and waived analytes." and "Note: Waived tests do not require proficient testing (PT). If a laboratory chooses to enroll waived test in PT, they must comply with all PT requirements, including the ban on improper PT referral." to this EP