The Joint Commission

Prepublication Requirements

• Issued June 20, 2024 •

Joint Commission Requirement

Standard Changes Resulting from Laboratory Redeeming Application

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 August 1, 2024

Accreditation Participation Requirements (APR) Chapter

APR.10.03.01

The laboratory complies with The Joint Commission's requirements addressing unsuccessful proficiency testing.
Note: ~~Unsuccessful proficiency testing is defined as a failure to achieve satisfactory performance for two consecutive or two out of three consecutive testing events. The following are considered unsatisfactory proficiency testing events:~~
~~- Failure to attain a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and D (Rho) typing and compatibility testing~~
~~- Failure to attain a score of 100% for ABO group and D (Rho) typing and compatibility testing~~
~~- Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider~~
~~- Omission of results on the proficiency testing form~~
~~- Failure to participate in a proficiency testing event~~

The laboratory complies with The Joint Commission's requirements addressing unsuccessful participation in proficiency testing.
Note: As defined by the Centers for Medicare & Medicaid Services in 42 CFR 493.2, unsuccessful participation in proficiency testing means any of the following:
- Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events
- Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty
- An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events
- Failure of a laboratory performing gynecologic cytology to meet the standard at 45 CFR 493.855

Element(s) of Performance for APR.10.03.01

EP 2 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The laboratory has failed to submit a written Plan of Action after two requests from The Joint Commission.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

Revised EP 2 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The laboratory has failed to submit a written Plan of Action after two requests from The Joint Commission.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement, including sustained satisfactory performance on two consecutive proficiency testing events, are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

EP 3 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The Plan of Action has not been found acceptable by The Joint Commission after three opportunities to provide an acceptable plan.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

Revised EP 3 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The Plan of Action has not been found acceptable by The Joint Commission after three opportunities to provide an acceptable plan.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement, including sustained satisfactory performance on two consecutive proficiency testing events, are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

EP 4 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The laboratory fails to achieve satisfactory performance on one of the next two consecutive proficiency testing events.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

Revised EP 4 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The laboratory fails to achieve satisfactory performance on one of the next two consecutive proficiency testing events.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement, including sustained satisfactory performance on two consecutive proficiency testing events, are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

EP 5 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The nature, scope, severity, and duration of the underlying issue warrants a cease in testing, such as nonsequential, but repeated, unsuccessful proficiency testing events.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

Revised EP 5 The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs: The nature, scope, severity, and duration of the underlying issue warrants a cease in testing, such as nonsequential, but repeated, unsuccessful proficiency testing events.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement, including sustained satisfactory performance on two consecutive proficiency testing events, are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

Document and Process Control (DC) Chapter

DC.02.01.01

The laboratory has procedures for each laboratory test.

Element(s) of Performance for DC.02.01.01

EP 1 Written laboratory procedures for each test meet the following requirements:
- They contain a complete description of the test.

- They include detailed instructions for performing the test.
- They adhere to manufacturers' instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory's current practice.
- They are readily available to staff performing the testing.

Note 1: Test procedures include, but are not limited to, the following:
- A step-by-step description of the performance of the procedure, including test calculations and interpretation of results
- Microscopic examination, including the detection of inadequately prepared slides
- Result entry in the patient clinical record
- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
- Control and calibration procedures
- Reference intervals (normal values)
- Reportable range
- Special precautions
- Limitations in the test methodology, including interfering factors
- Criteria for confirmatory testing
- Pertinent literature references

Note 2: An exception to including manufacturers' instructions is allowed when the laboratory establishes the performance specifications for test procedures with modifications to the manufacturer's instructions.

(See also LD.04.05.09, EPs 1, 2, 10)

Ⓓ Documentation is required

Revised EP 1 **Written laboratory procedures for each test meet the following requirements:**
- They contain a complete description of the test.
- They include detailed instructions for performing the test.
- They adhere to manufacturers' instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory's current practice.
- They are readily available to staff performing the testing.
Note 1: Test procedures include, but are not limited to, the following:
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- Microscopic examination, including the detection of inadequately prepared slides
- Result entry in the patient clinical record
- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
- Control and calibration procedures
- Calibration verification
- Reference intervals (normal values)
- Reportable range
- Special precautions
- Limitations in the test methodology, including interfering factors
- Criteria for confirmatory testing
- Pertinent literature references
Note 2: An exception to including manufacturers' instructions is allowed when the laboratory establishes the performance specifications for test procedures with modifications to the manufacturer's instructions.
(See also LD.04.05.09, EPs 1, 2, 10)

Ⓓ Documentation is required

DC.02.03.01

The laboratory report is complete and is in the patient's clinical record.

Element(s) of Performance for DC.02.03.01

EP 5 For interpretive reports, the qualified individual * providing the interpretation authenticates and signs out the results.
Note: Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key.
Footnote *: Qualifications of the individual providing interpretations are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 – §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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Human Resources (HR) Chapter

HR.01.01.01

The laboratory verifies staff qualifications.

Element(s) of Performance for HR.01.01.01

EP 3 The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities.
Note: Education and experience requirements are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~
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Ⓓ Documentation is required

HR.01.02.03

One or more qualified professionals direct pathology and clinical laboratory services.

Element(s) of Performance for HR.01.02.03

EP 1 The qualifications of the laboratory director * of record meet the requirements set forth in federal and state law and regulation.
Footnote *: Qualifications of the laboratory director are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~
(See also QSA.03.01.01, EP 1)

Revised EP 1 The qualifications of the laboratory director * of record meet the requirements set forth in federal and state law and regulation.
Footnote *: Qualifications of the laboratory director are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M.
(See also QSA.03.01.01, EP 1)

EP 3 A qualified individual * provides clinical consultation.
Note: In hospitals, it is preferable to have a pathologist providing clinical consultation.
Footnote *: Qualifications of the individual providing clinical consultation are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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EP 4 A qualified individual * directs clinical laboratory services.
Footnote *: Qualifications of the individual directing clinical laboratory services are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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EP 9 A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:
- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation.
- Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.
- Effective January 1, 2006, new embryology laboratory directors hold either High-Complexity Clinical Laboratory Director (HCLD) or Embryology Laboratory Director (ELD) certification from the American Board of Bioanalysis (AAB) or an equivalent board certification.
Note 1: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.
Note 2: If the embryology laboratory is also performing andrology ~~and~~ other testing specialties under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) guidelines, the laboratory director also meets CLIA qualifications. (For more information on the qualifications of the laboratory director, refer to HR.01.02.03, EP 1)
Note 3: If the medical director also serves as the laboratory director, they designate a laboratory supervisor. (For more information on embryology laboratory supervisor qualifications, refer to HR.01.03.01, EP 4)

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Note 1: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.
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Note 3: If the medical director also serves as the laboratory director, they designate a laboratory supervisor. (For more information on embryology laboratory supervisor qualifications, refer to HR.01.03.01, EP 4)

HR.01.02.05

The laboratory has the necessary staff to support the services it provides.

Element(s) of Performance for HR.01.02.05

EP 1 An individual qualified to provide technical consultation or supervision and general supervision * is on duty or is available whenever testing requires consultation or supervision.
Note: This individual can be available on site, by telephone, or by electronic consultation.
Footnote *: Qualifications to provide technical consultation or supervision and general supervision are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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HR.01.06.01

Staff are competent to perform their responsibilities.

Element(s) of Performance for HR.01.06.01

EP 3 An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence. *
Footnote *: Qualifications for this individual are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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Footnote *: Qualifications for this individual are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M.**

Leadership (LD) Chapter

LD.04.01.01

The laboratory complies with law and regulation.

Element(s) of Performance for LD.04.01.01

EP 2 The laboratory provides laboratory services in accordance with licensure requirements, laws, and rules and regulations.
~~Note: Laboratories that perform tests intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19 report all positive and negative test results on a daily basis to the appropriate state or local public health department.~~

Revised EP 2 The laboratory provides laboratory services in accordance with licensure requirements, laws, and rules and regulations.

LD.04.05.01

Laboratory leadership is effective.

Element(s) of Performance for LD.04.05.01

EP 5 All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

Revised EP 5 All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.
Note: Pathologists and laboratory personnel are permitted to review digital data, digital results, and digital images at a remote location under a primary location's CLIA certificate. For more information, refer to the memo from the Centers for Medicare & Medicaid Services' (CMS) Quality, Safety & Oversight Group; QSO-23-15-CLIA (https://www.cms.gov/files/document/qso-23-15-clia.pdf).

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 1 The laboratory participates in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program ~~*~~ that meets regulatory requirements for variety and frequency of testing. ~~**~~

~~Footnote *:~~ For information on current proficiency testing providers, see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.
~~Footnote **: For more information on proficiency testing, see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.~~
(See also LD.04.05.07, EP 4)

Ⓓ Documentation is required

Revised EP 1 The laboratory participates in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing. The laboratory notifies the US Department of Health and Human Services (HHS) of the approved program(s) in which it chooses to participate.
Note 1: If the laboratory participates in more than one proficiency testing program approved by CMS, the laboratory designates the program(s) to be used for each specialty, subspecialty, and analyte, or test.
Note 2: If a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte, or test, as defined in 42 CFR 493.803, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in 42 CFR 493 Subpart R.
Note 3: For information on proficiency testing and current proficiency testing providers, see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.
(See also LD.04.05.07, EP 4)

Ⓓ Documentation is required

EP 4 The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program ~~before the conclusion of a full calendar year~~, it notifies the Centers for Medicare & Medicaid Services (CMS) ~~or~~ The Joint Commission before this change is made.

Revised EP 4 The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program, it notifies the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission before this change is made.

EP 6 The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation.
Note: Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.

Revised EP 6 The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation.
Note 1: Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.
Note 2: Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

New EP 8 For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory undertakes appropriate training and employs the technical assistance necessary to correct problems associated with a proficiency testing failure. Remedial action is taken and documented.

Ⓓ Documentation is required

QSA.01.02.01

The laboratory maintains records of its participation in a proficiency testing program.

Element(s) of Performance for QSA.01.02.01

EP 4 The laboratory ~~retains proficiency testing records for at least two years from the date of participation for~~ the following proficiency testing events:
- Each proficiency testing result
- Test handling
- Preparation
- Processing
- Examination
- Each step in the testing
- Signed attestation statement(s) provided by the proficiency program
- A copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results
- Corrective action taken

Revised EP 4 The laboratory documents the following for all proficiency testing events:

- Each proficiency testing result
- Test handling for all samples
- Preparation for all samples
- Processing for all samples
- Examination for all samples
- Each step in the testing and reporting of results for all samples
- Signed attestation statement(s) provided by the proficiency program
- A copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results
- Remedial/corrective action taken
The laboratory retains proficiency testing records for at least two years from the date of the proficiency testing event.

QSA.01.03.01

The laboratory has a process for handling and testing proficiency testing samples.

Element(s) of Performance for QSA.01.03.01

EP 3 The laboratory performs proficiency testing for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate for each regulated analyte.
Note: Proficiency testing for secondary analyzers is not required.
(See also QSA.02.08.01, EP 1)

Revised EP 3 The laboratory performs proficiency testing for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate for each regulated analyte.
Note: Proficiency testing for secondary analyzers, test systems, assays, or examinations is not required.
(See also QSA.02.08.01, EP 1)

QSA.02.10.01

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.
Note: This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires that the combination of controls and calibrators used each day of testing be rotated to check normal, alkalosis, and acidosis levels).

Element(s) of Performance for QSA.02.10.01

EP 16 A qualified * individual assesses the staining quality of stains to determine their ability to correctly stain typical cellular characteristics and facilitate an accurate patient diagnosis. The assessment is documented.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

(D) Documentation is required

Revised EP 16 A qualified * individual assesses the staining quality of stains to determine their ability to correctly stain typical cellular characteristics and facilitate an accurate patient diagnosis. The assessment is documented.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M.

(D) Documentation is required

QSA.05.01.01

The laboratory has written policies and procedures for the blood transfusion service.

Element(s) of Performance for QSA.05.01.01

EP 4 The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology * conducts a review of the policies and procedures of the blood transfusion service every two years. The review is documented.
Note: A designee is not permitted to conduct this review.
Footnote *: Qualifications for a technical supervisor in immunohematology are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

(D) Documentation is required

Revised EP 4 The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology * conducts a review of the policies and procedures of the blood transfusion service every two years. The review is documented.
Note: A designee is not permitted to conduct this review.
Footnote *: Qualifications for a technical supervisor in immunohematology are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M.

(D) Documentation is required

QSA.05.02.01

A supply of blood and blood components that meets the needs of the patients, the services provided by the organization, and the clinical staff is available at all times to the organization.

Element(s) of Performance for QSA.05.02.01

EP 3 ~~A~~ written agreement with a blood supplier includes the following:
- The responsibilities of both parties and approval by the transfusion service director or administrator
- The process for procurement, transfer (including transport), and availability of blood and blood components if the laboratory itself does not provide blood banking services on site
- The notification by the blood supplier to the laboratory's transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV)

(D) Documentation is required

Revised EP 3 The laboratory has a written transfusion service agreement with a blood supplier that is reviewed and approved by the responsible parties. The transfusion service agreement includes the following:
- The responsibilities of both parties and approval by the transfusion service director or administrator
- The process for procurement, transfer (including transport), and availability of blood and blood components if the laboratory itself does not provide blood banking services on site
- The notification by the blood supplier to the laboratory's transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV)

(D) Documentation is required

QSA.05.09.01

The laboratory has policies and procedures for serologic and computer (if performed) compatibility testing of donor blood with recipient blood.

Element(s) of Performance for QSA.05.09.01

EP 2 Policies and procedures for compatibility testing include the following:
- A determination of recipient ABO Group and Rh type
- A serologic and computer (if performed) crossmatch protocol
- An antibody screening protocol
- Actions to be taken in cases of positive antibody screens and direct antiglobulin tests
- Actions to be taken in cases of incompatible crossmatches
- A time frame during which a sample may be used for crossmatching before obtaining a new sample
- A time frame not to exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.

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- A time frame not to exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.
Policies and procedures are in accordance with manufacturers' instructions and 21 CFR 606.151, as applicable.

QSA.08.01.01

The laboratory director or the cytology technical supervisor determines qualifications and number of cytology staff.

Element(s) of Performance for QSA.08.01.01

EP 1 The laboratory director or cytology technical supervisor determines cytology staff qualifications. * Footnote *: Qualifications for cytology staff are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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Footnote *: Qualifications for cytology staff are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M.

EP 2 The laboratory complies with federal and state personnel qualification and licensure requirements. * Footnote *: Qualifications for cytology personnel are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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QSA.08.03.01

The cytology technical supervisor uses quality improvement processes to measure, assess, and improve the cytology service.

Element(s) of Performance for QSA.08.03.01

New EP 11 The cytology technical supervisor evaluates the case reviews of each individual examining slides against the laboratory's overall statistical values. Any discrepancies are documented, including reasons for the deviation, and, if appropriate, corrective actions taken.

Ⓓ Documentation is required

QSA.08.06.01

The cytology quality system includes review of a random sample of negative gynecologic slides.

Element(s) of Performance for QSA.08.06.01

EP 1 A qualified * individual reviews a random sample of negative gynecologic slides before reporting patient results. The review is documented.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

Ⓓ Documentation is required

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Ⓓ Documentation is required

EP 3 A qualified * individual completes the review of a random sample of negative gynecologic slides before reporting patient results.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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QSA.13.04.01

Surgical specimens sent to the laboratory are examined by or under the supervision of a qualified individual.

Element(s) of Performance for QSA.13.04.01

EP 2 When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The nonpathologist meets the qualifications for high-complexity testing personnel. *
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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EP 5 An individual qualified * in anatomic pathology evaluates each microscopic section.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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EP 6 For Mohs testing, an individual qualified * in anatomic pathology or a qualified dermatologist evaluates each microscopic section.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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EP 7 The diagnosis for each surgical specimen is made by or under the supervision of a qualified * individual.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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QSA.13.06.01

The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

Element(s) of Performance for QSA.13.06.01

EP 1 A pathologist qualified * in anatomic pathology assesses the staining quality (for example, equipment, methods, stains) of microscopic tissue sections to determine the stain's ability to facilitate a diagnosis. The staining quality assessments are documented.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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EP 2 The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented.
Note: For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. ~~For polymer-based immunohistochemical methods, a negative control is not required.~~
(See also QSA.13.08.01, EP 1)

Ⓓ Documentation is required

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(See also QSA.13.08.01, EP 1)

Ⓓ Documentation is required

EP 4 The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each time the procedure is performed. The quality control results are documented.
~~Note: For polymer-based immunohistochemical methods, a negative control is not required.~~

Ⓓ Documentation is required

Revised EP 4 The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each time the procedure is performed. The quality control results are documented.

Ⓓ Documentation is required

QSA.15.03.03

The laboratory uses quality control materials to verify each test run of patient samples for molecular testing.

Element(s) of Performance for QSA.15.03.03

EP 4 For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses a control material capable of detecting the inhibition. The quality control results are documented.

Ⓓ Documentation is required

Revised EP 4 For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses an additional control material capable of detecting the inhibition. The quality control results are documented.

Ⓓ Documentation is required

QSA.15.05.01

The laboratory's molecular testing reports include specific testing information.

Element(s) of Performance for QSA.15.05.01

EP 4 Molecular testing reports filed in the patient's clinical record that require specific interpretation are authenticated by the individual qualified * by the Clinical Laboratory Improvement Amendments (CLIA '88) to make the interpretation.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at ~~https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.~~

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