The Joint Commission

Prepublication Requirements

• Issued October 21, 2024 •

Joint Commission Requirement

New and Revised Laboratory Requirements Related to Histocompatibility

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

Human Resources (HR) Chapter

HR.01.04.01

The laboratory provides orientation to staff.

Element(s) of Performance for HR.01.04.01

New EP 11 **The laboratory has a documented training program that makes sure staff have the following skills prior to analyzing patient specimens:**
- Proper preanalytic knowledge, including specimen collection; patient preparation, if applicable; and the labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of all specimens
- Ability to perform all standard laboratory procedures
- Ability to perform each test method, including proper instrument use
- Ability to perform preventive maintenance, troubleshooting, and calibration procedures related to each test performed
- A working knowledge of reagent stability and storage
- Ability to implement laboratory quality control policies and procedures
- Knowledge of the factors that influence test results
- Ability to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results

Ⓓ **Documentation is required**

Leadership (LD) Chapter

LD.04.05.01

Laboratory leadership is effective.

Element(s) of Performance for LD.04.05.01

New EP 3 **The laboratory director is onsite at the laboratory at least once every six months, with at least four months between the minimum two onsite visits.**
Note 1: The laboratory director is accessible to the laboratory to provide onsite, telephone, or electronic consultation as necessary.
Note 2: The onsite visits are documented and include evidence of performing activities that are part of the laboratory director's responsibilities.
Note 3: The laboratory director makes certain that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 42 CFR 493.1489(b)(5).

Ⓓ **Documentation is required**

New EP 10 **The PPM laboratory director is responsible for the following:**
- Evaluating the competency of all testing personnel to ensure that the staff maintains their competency to perform test procedures and report tests promptly, accurately, and proficiently.
- Evaluating and documenting the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.
Note: The procedures for evaluation of the competency include but are not limited to the following:
- Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing
- Monitoring the recording and reporting of test results
- Review of test results or worksheets
- Assessment of test performance through testing internal blind testing samples or external proficiency testing samples
- Assessment of problem solving skills

Ⓓ **Documentation is required**

Quality System Assessment for Nonwaived Testing (QSA) Chapter

QSA.12.01.01

The laboratory uses quality control practices and validation methods for histocompatibility testing.

Element(s) of Performance for QSA.12.01.01

EP 6 ~~For~~ immunologic reagents ~~(for example, antibodies, antibody-coated particles, complement) that~~ facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the laboratory monitors the efficacy of the methods with quality control procedures.

Revised EP 6 If the laboratory uses immunologic reagents to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the laboratory monitors the efficacy of the methods with quality control procedures.

EP 8 The laboratory ~~has a system in place for proper storage and maintenance of both recipient sera and reagents at an acceptable temperature range for sera and components, including a temperature alarm system and an emergency plan for alternative storage~~.

Revised EP 8 The laboratory uses a continuous monitoring and alert system to monitor the storage temperature of specimens (donor and recipient) and reagents. The system notifies laboratory staff when temperature limits are exceeded.

New EP 15 The laboratory develops and implements written policies and procedures for the storage and retention of specimens based on the specific type of specimen.
Note 1: All specimens are easily retrievable.
Note 2: The laboratory has an emergency plan for alternate storage.
(See also DC.01.03.01, EP 4)

Ⓓ **Documentation is required**

New EP 16 The laboratory participates in at least one national or regional cell exchange program. If a program is unavailable, the laboratory develops an exchange system with another laboratory to validate interlaboratory reproducibility.

Ⓓ **Documentation is required**

Current QSA.12.02.01 through QSA.12.07.01 were deleted and replaced with the following

QSA.12.02.01

The laboratory performs human leukocyte antigen (HLA) typing.

Element(s) of Performance for QSA.12.02.01

New EP 1 **The laboratory uses human leukocyte antigen (HLA) terminology that conforms to the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System.**

New EP 2 **The laboratory develops and implements written criteria for determining when antigen and allele typing are required.**

Ⓓ **Documentation is required**

QSA.12.03.01

The laboratory performs human leukocyte antigen (HLA) serologic antibody screening and identification.

Element(s) of Performance for QSA.12.03.01

New EP 1 **The laboratory makes a reasonable effort to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening, identification, and crossmatch.**

Ⓓ **Documentation is required**

QSA.12.04.01

The laboratory crossmatches potential recipients and donors before transplantation is performed.

Element(s) of Performance for QSA.12.04.01

New EP 1 **The laboratory develops and implements written policies and procedures for performing a crossmatch that include the following:**
- Definition of donor and recipient human leukocyte antigen (HLA) antigens, alleles, and antibodies tested
- Criteria necessary to assess a recipient's alloantibody status
- Criteria for assessment of recipient antibody presence or absence on an ongoing basis
- Criteria for typing the donor to include the HLA antigens to which antibodies have been identified in the potential recipient, as applicable
- Descriptions of the circumstances in which pre- and post-transplant confirmation testing of donor and recipient specimens is required
- Requirements for the availability all applicable donor and recipient test results to the transplant team
- Requirements to ensure that the immunologic assessments are based on test results obtained from a test report from a CLIA- certified laboratory
- Defines time limits between recipient testing and the performance of a crossmatch

Ⓓ **Documentation is required**

New EP 2 **The test report specifies the type of crossmatch performed.**

Ⓓ **Documentation is required**

QSA.12.05.01

If the laboratory performs histocompatibility testing for infusion and transplantation purposes, it develops and implements written policies and procedures specifying the histocompatibility testing (HLA typing, antibody screening and identification, and crossmatching) to be performed for each type of cell, tissue, or organ to be infused or transplanted.

Element(s) of Performance for QSA.12.05.01

New EP 1 **If the laboratory performs histocompatibility testing for infusion and transplantation purposes, it develops and implements written policies and procedures specifying the histocompatibility testing to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory's policies and procedures must include testing protocols that address:**
- Transplant type (organ, tissue, cell)
- Donor (living, deceased, or paired)
- Recipient (high risk vs. unsensitized)
- Type and frequency of testing required to support clinical transplant protocols
- Process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant and prior to transplantation
Note: If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory has a process to document its efforts to obtain the specimen.

Ⓓ **Documentation is required**

QSA.12.06.01

The laboratory documents all control procedures performed related to histocompatibility testing.

Element(s) of Performance for QSA.12.06.01

New EP 1 The laboratory documents all control procedures performed related to histocompatibility testing.

Ⓓ Documentation is required

QSA.13.07.01

The laboratory retains histological specimens for patient care purposes.

Element(s) of Performance for QSA.13.07.01

EP 2 Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are retained in accordance with law and regulation and as defined by organization policy.
Note 1: Minimum retention requirements in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations are defined as follows:
- Microscopic slides, including stained slides, are retained for at least 10 years.
- Paraffin blocks are stored for at least two years from the date of the examination.
- Gross tissue specimens are retained for at least seven days after required microscopic sections are examined and reports are reviewed and signed.
Note 2: Individual state law and regulation for retention requirements may vary. The most stringent guidelines should be followed.

Revised EP 2 Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are retained in accordance with law and regulation and as defined by organization policy.
Note 1: Minimum retention requirements in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations are defined as follows:
- Microscopic slides, including stained slides, are retained for at least 10 years.
- Paraffin blocks are stored for at least two years from the date of the examination.
- Gross tissue specimens are retained for at least seven days after required microscopic sections are examined and reports are reviewed and signed by an individual qualified under 42 CFR 493.1449(b), (f), or (g).
Note 2: Individual state law and regulation for retention requirements may vary. The most stringent guidelines should be followed.
Note 3: 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.