
Fast Focus on Compliance

2016 Histocompatibility Checklist Edition changes affecting
UNOS member laboratories

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Rationale for Changes

- OPTN/UNOS Board of Directors approved new policies for histocompatibility testing required for solid organ transplantation.
- These revisions were made in order to educate the applicable histocompatibility community of the changes.

Major Topics Include

- HLA Testing
- Written Agreements with Transplant Programs and Organ Procurement Organization
- Laboratory Coverage
- Continuing Education Hours

Requirement ID	Requirement	Key Points
HSC.21281	<p data-bbox="394 724 974 756">Accreditation of Reference Laboratory</p> <p data-bbox="394 792 1491 850">Outside reference laboratories are accredited by appropriate histocompatibility agencies, and for US laboratories, CLIA certified or meet equivalent requirements as determined by CMS.</p> <p data-bbox="394 883 1491 941">NOTE: Laboratories that are members of the United Network for Organ Sharing (UNOS) may only refer histocompatibility testing to other laboratories that are OPTN-approved.</p> <p data-bbox="394 974 1491 1032">Refer to GEN.41350 for additional information on requirements for reference laboratory selection.</p> <p data-bbox="394 1065 709 1097">Evidence of Compliance:</p> <p data-bbox="394 1097 1428 1130">✓ Records verifying reference laboratory certification/accreditation in histocompatibility</p> <p data-bbox="394 1162 575 1195">REFERENCES</p> <p data-bbox="441 1195 1444 1278">1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.</p>	<p data-bbox="1533 724 1902 850">• OPTN member laboratory must verify OPTN-approval of outside reference laboratory</p>



HSC.28186

Serologic Typing - Class I

Phase II

Target cells are defined for serological determination of HLA Class I antigens, and selected to permit typing the antigens officially recognized by the WHO Committee for which reagents are readily available.

NOTE: HLA Typing for all deceased organ donors must be performed by molecular methods. Serological determination of HLA Class I antigens should be performed on T cells by appropriate documentation of HLA specificity, using cells of or mononuclear cell preparations. Local serological typing reagents must be supported known HLA types. The test must detect WHO recognized specificities.

HSC.28373

Serologic Typing - Class II

Phase II

The methodology for serological Class II antigen typing defines the proportion of B-cells needed for optimal testing, and the specificities that are officially recognized by the WHO Committee and for which reagents are readily available.

NOTE: The method should produce at least 80% B-cell enriched. Documentation of B cell enrichment may not be necessary when procedural techniques already distinguish T- and B-lymphocytes, or when well-characterized antibodies are used that can only discriminate and identify Class II antigens. HLA typing for all deceased organ donors must be performed by molecular methods.

REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.
- 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):[42CFR493.1278(b)] and [42CFR493.1278(5)(iii)]

- OPTN member laboratory must use molecular procedures to perform HLA typing for all deceased organ donors
- Patient report indicates the molecular test method used



HSC.33983

HLA Typing Level of Resolution

Phase II

The level of resolution of HLA typing is adequate for the clinical programs supported.

NOTE: When performing HLA typing of deceased organ donors, all of the following types are required to be reported for: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, and DPB.

REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.
- 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24):7170 [42CFR493.1278(b)(2)]

- OPTN member laboratory must report indicated HLA types for all deceased organ donors



HSC.39430

Written Agreements

Phase II

There are written agreements for histocompatibility testing with each transplant program and organ procurement organization (OPO) served by the laboratory, unless clinical urgency prevents such an agreement.

NOTE: If the laboratory participates as a member of the United Network for Organ Sharing (UNOS), the written agreements must address all elements defined in the most current version of the Organ Procurement and Transplantation Network (OPTN) Bylaws. The following elements are defined in the March 1, 2016 OPTN Bylaws:

The agreement with transplant programs and OPOs must include the following:

- Specimen requirements for typing and crossmatching
- Loci and level of resolution typed
- Process for requesting extended HLA typing
- Process for reporting HLA typing results to UNOS
- Process for resolving HLA discrepancies and errors
- Turnaround time from sample receipt to reporting to transplant program or OPO
- Length of specimen retention for repeat or future testing

Agreements with the transplant program must also include the following:

- Process for reporting and verifying HLA and other data at the time of registration on the waiting list and where there are changes
- Process to obtain sensitization history
- Frequency of periodic sample collection
- Frequency for antibody screening
- Criteria for crossmatch
- Assay format used for antibody screening and crossmatching
- Criteria for determining unacceptable antigens used during organ allocation
- Protocol for monitoring antibody levels if desensitization is used
- Process for blood type verification if the laboratory registers candidates for the transplant program
- Protocol for monitoring antibody levels if post-transplant monitoring is performed

Agreements with OPOs must also include the following:

- Process for prioritizing donors for histocompatibility testing
- All methods used for crossmatching, interpretation, and reporting of results if crossmatching is done by the OPO

- OPTN member laboratory must include OPTN bylaw elements in Transplant written agreement



REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.

HSC.39499

Laboratory Coverage Plan

Phase II

The laboratory coverage plan for staffing ensures that qualified testing personnel and key personnel are available to perform histocompatibility testing for organ transplantation and to facilitate organ acceptance and transplantation as needed.

NOTE: For laboratories that are members of the United Network for Organ Sharing (UNOS), the following staff availability requirements from the OPTN Bylaws apply:

- Key personnel include the laboratory director, technical supervisor, general supervisor, and the clinical consultant
- The plan must include coverage at all times, including when changes occur in key personnel, and address coverage when key personnel serve more than one laboratory
- If the laboratory performs testing on deceased organ donors, key personnel and qualified testing personnel must be available 24-hours a day, seven days a week, unless an alternative coverage plan has been approved by UNOS/OPTN Membership and Professional Standards Committee

Evidence of Compliance:

- ✓ Staffing schedule **OR** on-call schedule if 24-hour staffing is not available

REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.

OPTN member laboratory staffing policy must address laboratory coverage to include:

- Qualified testing personnel at all times
- Availability of key personnel at all times
- Key personnel are section director/technical supervisor, general supervisor and/or clinical consultant

Work schedules may demonstrate evidence of compliance



HSC.40100

Notification of Change in Key Personnel

Phase II

If the histocompatibility laboratory participates as a member of the United Network for Organ Sharing (UNOS), there is a policy to notify the CAP's Laboratory Accreditation Program when there is a change in **key personnel, including the section director/technical supervisor, general supervisor, and/or clinical consultant.**

NOTE: Notification must occur no later than 30 days prior to the change; or in the case of an expected change, no later than 2 working days afterwards. **For changes in laboratory directorship, refer to GEN.26791.**

REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.

- OPTN member laboratory policy must address the notification to CAP when key personnel change
- Key personnel are section director/technical supervisor, general supervisor and/or clinical consultant
- Current status of Key personnel and notification documentation to CAP may demonstrate evidence of compliance

HSC.47500

Continuing Education Program

Phase II

There is a continuing clinical laboratory education program that addresses the areas of service offered by the laboratory, **identifies the need for remedial training, where appropriate, and provides continuing education to improve skills in histocompatibility.**

NOTE: The laboratory must have a complete continuing clinical laboratory education program that meets the needs of the various types of laboratory personnel and addresses the areas of service offered by the laboratory, **including a predefined minimum number of contact hours annually. This program may be provided locally, regionally/nationally, through scientific article review and discussion, or some combination of the above.**

Evidence of Compliance:

- ✓ Written policy for continuing education requirement for all personnel **AND**
- ✓ Records of continuing education

REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.

- Although UNOS does not define the specific number of CE hours required, laboratories must have a continuing education program sufficient to meet the needs of the laboratory.
- OPTN member laboratory must predefine the number of CE hours required of laboratory staff



Scenario

A newly graduated medical technologist is hired to work in a Histocompatibility Laboratory. After successful completion of training and proper test performance, the employee begins independent patient testing. The employee continues to demonstrate quality testing and reports patient results accurately. The semiannual competency assessment demonstrates that the employee is competent.

Question: This employee has less than one year experience in histocompatibility. Is this individual qualified to work independently in the Histocompatibility laboratory if a qualified supervisor is available by phone, as needed?

- A. Yes, based on the education and the results of the semiannual competency assessment.
- B. No, a supervisor must be present at all times during testing and reporting.
- C. Yes, if a qualified supervisor is available by phone, as needed.

Scroll to the next page for the correct answer.



Correct answer is C. Yes. Newly hired testing personnel who are adequately trained and have successfully demonstrated competency in proper test performance may perform testing in the absence of an on-site supervisor if this follows laboratory policy; however, the individual must have access to a supervisor and/or personnel meeting the requirements of HSC.45000. The laboratory coverage plan (HSC.39499) must allow for appropriate provisions for staffing.

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HSC.45000

Testing Personnel Qualifications

Phase I

Personnel performing the technical work of histocompatibility have at least one year of training and/or experience in histocompatibility and qualify as high complexity testing personnel with a minimum of the following:

- 1) Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology; or
- 2) Associate degree in a laboratory science or medical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in the CLIA regulation 42CFR493.1489. The qualifications to perform high complexity testing can be accessed using the following link: [CAP Personnel Requirements by Testing Complexity](#).

NOTE: Persons with less than one year of training and/or experience must work under the supervision of persons who are qualified.

Evidence of Compliance:

- ✓ Records of qualifications including degree or transcript, current laboratory personnel license (if required), and work history in related field

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 1992(Feb 28):7175 [42CFR493.1423], 7183 [42CFR493.1489]
- 2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. March 1, 2016.

