1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

HSC.39850 CD34 Cellular Viability - Apheresis and Cord Blood Products Phase II

The laboratory measures the viability of CD34 positive cells in samples aliquoted at the time of processing of hematopoietic progenitor cells, apheresis products and cord blood products.

NOTE: CD34 cell viability testing of cord blood products must be done on a sample aliquoted prior to the addition of cryoprotectant.

For any hematopoietic progenitor cell product, CD34 cell viability testing during or after storage should be considered as an additional quality control.

The viability dye 7-amino actinomycin-D (7-AAD) yields excellent results in this analysis. The viability assay must be performed using a flow cytometric method with the viability dye included in the same tube with the CD34 and CD45 monoclonal antibodies for the CD34+ viability determination. Estimates of total cellular viability (for example, trypan blue exclusion) may not be used as an alternative because the method can overestimate the viability of the CD34 stem cell population.

REFERENCES

1) Owens M, Loken M. Peripheral blood stem cell quantitation, In Flow Cytometry Principles for Clinical Laboratory Practice. New York, NY: Wiley-Liss, 1995:111-127
2) Keeney M., *et al.* Single platform flow cytometry absolute CD34+ cell counts based on the ISHAGE guidelines. *Cytometry.* 1998; 34:61-70
3) Hubl W., *et al.* Measurement of absolute concentration and viability of CD34+ cells in cord blood and cord blood products using fluorescent beads and cyanine nucleic acid dyes. *Cytometry.* 1998; 34:121-127
4) Gratama J., *et al.* Flow cytometric enumeration of CD34+ hematopoietic stem and progenitor cells. *Cytometry.* 1998;34:128-145
5) Lee S., *et al.* Post-thaw viable CD34+ cell count is valuable predictor of haematopoietic stem cell engraftment in autologous peripheral blood stem cell transplantation. *Vox Sang* Feb: 2008; 94:46-152
6) Riech-Slotky R., *et al.* Determining post-thaw CD34+ cell dose of cryopreserved haematopoietic progenitor cells demonstrates high recovery and confirms their integrity. *Vox Sang* 2008: May; 94(4):351-357
7) Clinical and Laboratory Standards Institute. *Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline.* 2nd ed. CLSI Document H42-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2007.

PERSONNEL

Inspector Instructions:

READ	• Records of section director (technical supervisor), testing personnel, and clinical consultant education and experience • Continuing education policy • Sampling of continuing education records
ASK	• Has there been any changes in the histocompatibility section director or key personnel in the last two years?

***REVISED** 12/26/2024*

HSC.40000 Section Director/Technical Supervisor Qualifications - Histocompatibility Phase II

The section director (technical supervisor) of the histocompatibility section has the following qualifications.

1. MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located, OR doctoral degree in biological, clinical or medical laboratory science,

or medical technology from an accredited institution, OR meet the educational requirement found in CLIA regulation §42CFR493.1443(b)(3)(i)(B); AND

2. **Four years training and experience in histocompatibility, OR two years training and experience in general immunology plus two years in histocompatibility. For section director/technical supervisors supporting solid organ and/or hematopoietic progenitor cell transplantation, records of training or relevant experience in histocompatibility appropriate to the supported transplant program(s)**

NOTE: The training and experience must relate to testing of human specimens for the purpose of diagnosing, treating, and monitoring an individual's condition. Individuals qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, may continue to fill this role if they have done so continuously since December 28, 2024. More detailed information on Section Director/ Technical Supervisor qualifications can be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed.

If there is a change in the histocompatibility section director, the laboratory must notify the CAP as required in HSC.40100. If the new section director has not been previously accepted by the CAP (either by CAP evaluation or by evidence of prior directorship of a CAP-accredited histocompatibility laboratory for the same types of services), the laboratory must submit records to the CAP for review, including the new section director's curriculum vitae and portfolio, or evidence that the portfolio has been reviewed and approved by a certifying board (eg, ACHI). If the new section director is accepted by the CAP, a letter is sent to the laboratory director. The letter must be retained and be provided to inspectors upon request. If the CAP does not accept the section director, another section director meeting CAP qualifications must be assigned.

The CAP's review of a new section director includes an evaluation of the individual's education, training, and experience for acceptability with the laboratory's scope of service (activity menu). Where indicated, the CAP may require submission of a portfolio of cases consistent with the laboratory's scope of service, which includes cases covered during the previous five years demonstrating analytical skills, ability to recognize and resolve testing and interpretation issues, and instances where recommendations were made for additional testing or clinical care including:

- *At least 20 solid organ transplant cases for solid organ transplant (10 in detail and a log of 20 total)*
- *If the laboratory participates as a member of UNOS/OPTN, at least 50 cases for solid organ transplantation (10 in detail and a log of 50 total)*
- *At least 20 hematopoietic progenitor cell transplant cases representative of the program mix of related and unrelated transplants (10 in detail and a log of 20 total) and/or*
- *At least 10 cases for other histocompatibility testing (eg, pharmacogenomics, disease association, transfusion support).*

If the laboratory participates as a member of the United Network for Organ Sharing (UNOS), the CAP may require submission of additional records based on the qualifications of the new section director to demonstrate compliance with the Organ Procurement and Transplantation Network (OPTN) Bylaws: Appendix C for approval, including the following:

- *Proof of active interaction with transplant professionals*
- *A statement explaining all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed*
- *A current curriculum vitae*
- *Participation in transplant or clinical laboratory professional conferences or publications in peer-reviewed journals*

Evidence of Compliance:

- ✓ Records of section director/technical supervisor qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation (eg, ACHI certified Fellow/Affiliate,

previously ASHI-DTRC approved laboratory director), board certification (eg, Diplomate ACHI (ABHI), ABMLI), or current license (if required) **AND**
- ✓ Work history in related field **AND**
- ✓ CAP letter of acceptance for new histocompatibility section directors

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1449(h)].
2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

***REVISED** 08/24/2023*

HSC.40100 Notification of Change in Key Personnel **Phase II**

The laboratory notifies the CAP's Laboratory Accreditation Program when there is a change in the histocompatibility director (technical supervisor) and other key personnel, as applicable.

NOTE: All laboratories must notify the CAP when there is a change of histocompatibility section director and submit records for review by the CAP as requested.

Histocompatibility testing laboratories that participate as a member of the United Network for Organ Sharing (UNOS) must also notify the CAP when there is a change in other key personnel, including the general supervisor and/or clinical consultant.

Notification must occur no later than 30 days prior to the change; or in the case of an unexpected 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. December 5, 2022.

***REVISED** 12/26/2024*

HSC.45000 Testing Personnel Qualifications - Histocompatibility **Phase II**

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, biological, clinical or medical laboratory science, or medical technology from an accredited institution; 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 GEN.54750 for high complexity testing.**

NOTE: A more detailed listing of personnel qualifications can be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

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 section director/technical supervisor qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, board certification, or current 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.* 2023(Dec 28):[42CFR493.1489].
2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.