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<br>• Continuing education policy<br>• 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,**