HSC.39219 Donor Typing for Solid Organ Transplant **Phase I**

Donor materials obtained pre-organ recovery are used whenever possible for donor HLA typing and recipient serum screening.

NOTE: Organ donors should be HLA-typed from any acceptable source of viable lymphocytes. Whenever possible, pre-organ recovery HLA testing and screening crossmatches should be done.

Evidence of Compliance:

✓ Record of typing and screening on pre-organ donor materials, when possible

HSC.39406 Donor and Recipient HLA Typing **Phase II**

The HLA laboratory types all potential recipients and donors referred to the laboratory, and follows policies defining when HLA retyping and redefinition are required.

Evidence of Compliance:

✓ Records of all HLA typing

REFERENCES

1) 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]

HSC.39410 HLA Typing Post Transfusion **Phase II**

The laboratory has a defined process for actions to be taken when a donor or patient cannot be reliably HLA typed after transfusion.

NOTE: Transfusions may result in detection of additional HLA antigens and/or alleles in donor or patient samples. Alternative source typing material (eg, buccal swab, lymph node or spleen) may be considered if more than two antigens are detected for a locus or alleles cannot be discriminated. Typing must be performed at the level of resolution required for the transplant service being supported.

HSC.39415 HLA Typing Level **Phase II**

The laboratory performs HLA typing at least to the minimal resolution appropriate for the individual transplant program supported (*eg,* 2-field typing for hematopoietic progenitor cell transplantation, when appropriate, and the level of serological splits for solid organ transplantation).

Evidence of Compliance:

✓ Patient reports and typing records

REFERENCES

1) Nunes E., et al. Definitions of histocompatibility typing terms: Harmonization of Histocompatibility Typing Terms Working Group. *Hum Immunol.* 2011; 72(12):1214-6; *Blood* 2011; 118:e180-3.
2) Organ Procurement and Transplantation Network (OPTN) Policies. Policy 4: Histocompatibility. US Department of Health and Human Services. Effective Date: December 5, 2022.
3) National Marrow Donor Program. NMDP Policy for HLA Confirmatory Typing Requirements for Unrelated Adult Donors and HLA Typing Requirement for Patients. Document Number: P00079. Effective date: February 27, 2021.

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

HSC.39430 Written Agreements **Phase II**

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

NOTE: Written agreements must be reviewed biennially by the histocompatibility section director/ technical supervisor, and/or clinical consultant, and the clinical transplant program director, and be revised as necessary.

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 Organ Procurement and Transplantation Network (OPTN) Bylaws when applicable:

- *The sample requirements for typing and crossmatching*
- *The loci and level of resolution typed*
- *A process for requesting extended HLA typing*
- *A process for reporting and verifying HLA and unacceptable antigen data at the time of registration on the waiting list and any time there are changes*
- *A process for reporting HLA typing results to the OPTN Contractor*
- *A process for resolving HLA typing discrepancies and errors*
- *The maximum turnaround time from receipt of sample to reporting of results to the transplant program*
- *A process to obtain sensitization history for each patient*
- *The frequency of periodic sample collection*
- *The frequency of antibody screenings*
- *The criteria for crossmatching including the optimal time limits between recipient testing and crossmatch performance*
- *The assay format that will be used for antibody screening and for crossmatching*
- *The criteria for determining unacceptable antigens used during organ allocation*
- *The duration for which specimens need to be stored for repeat or future testing*
- *If desensitization is performed, a protocol for monitoring antibody levels*
- *If the laboratory registers candidates for the transplant process, a process for blood type verification*
- *If post-transplant monitoring is performed, a protocol for monitoring antibody levels.*

If the laboratory supports a program or donor registry that is accepted through the Foundation for the Accreditation of Cellular Therapy (FACT), the agreements must contain the requirements defined in the 7th edition of the FACT Standards.

If a laboratory supports a program or donor registry that is participating in the National Marrow Donor Program (NMDP)/Be The Match, the agreement must contain the provisions defined in the November 2017 NMDP U.S. Transplant Center Participation Criteria.

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*

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.
2) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.
3) National Marrow Donor Program (NMDP)/Be The Match. US Transplant Center Participation Criteria. Document #A00228. Effective January 30, 2023.

HSC.39450 Histocompatibility Testing Requests — Phase II

There are records of histocompatibility testing requests not covered by the transplant program support agreement.

NOTE: The laboratory has records of HLA testing requests which deviate from or are not covered in the existing transplant program support agreement (eg, the use of serum for a final crossmatch that is "too old" or "no final crossmatch" for a patient who would normally require a crossmatch within a previously defined time before transplant).