

The method of probe labeling is validated to detect the target sequence without a false positive signal for non-target sequences.

Evidence of Compliance:

- ✓ Records of in-house validation study data

HSC.37910 Re-Probing

Phase II

If re-probing a solid-phase nucleic acid sample is performed, there are records of complete stripping of the previous probe before re-probing.

MOLECULAR HLA TYPING

HSC.38060 HLA Typing Level of Resolution

Phase II



The level of resolution of HLA typing is adequate for the clinical programs, including donor registries, and the type of cell, tissue, or organ to be transplanted and meets the requirements of relevant accrediting agencies.

NOTE: Laboratories performing testing for NMDP donors must follow NMDP policies for resolution of typing ambiguities. Alternative allele combinations must be resolved when they contain one or more alleles in the common or intermediate categories of the CIWD 3.0.0 catalog.

For hematopoietic progenitor cell transplant, the laboratory must perform HLA typing at the level of resolution and including the loci required by the agreements with the transplant center and/or donor registry. For example, high resolution typing of HLA-A, B, C, DRB1 and DPB1 is mandatory for patient and unrelated donor matching per NMDP.

When performing HLA typing of deceased donors for the purpose of solid organ allocation in the United States, report the following loci as required by OPTN policies: A, B, Bw4, Bw6, C, DRB1, DRB3/4/5, DQA1, DQB1, and DPB1.

REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Policies. Policy 4: Histocompatibility. US Department of Health and Human Services. Effective Date: 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.
- 4) 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.
- 5) Hurley CK, et al. Common, intermediate and well-documented HLA alleles in world populations: CIWD version 3.0.0. *HLA*. 2020;95(6):516-531.

HSC.38097 Sequence-Based Typing

Phase II



For sequence-based typing, there are records of the following:

- **Templates with sufficient specificity for a locus or allele**
- **Appropriate monitoring of all steps**
- **Adequate electrophoretogram quality to support the sequence results**
- **Definition of a sequence following a procedure for accurate assignment of HLA alleles**

NOTE: Records must include the HLA locus and allele specificity of the template, the source of the sequence data base used (annually updated), and procedures to resolve ambiguous combinations. Assignment of alleles for HLA loci must be done by comparing the sequence data with the sequences of all alleles that are recognized by the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System.