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.

Laboratories must recognize ambiguous allele combination(s) and resolve these as appropriate for the clinical use as defined by the transplant agreement.

***NEW** 12/26/2024*

HSC.38098 IPD-IMGT/HLA Database **Phase I**

For molecular HLA typing, when applicable, the laboratory maintains records that include the IPD-IMGT/HLA or similar database version number at the time of testing.

NOTE: IPD-IMGT/HLA or similar database for HLA type reporting must be reviewed at least annually and updated if applicable.

REFERENCES

1) European Molecular Biology Laboratory-European Bioinformatics Institute (EMBL-EBI). IPD-IMGT/HLA. EMBL-EBI website. Accessed January 26, 2024. https://www.ebi.ac.uk/ipd/imgt/hla/
2) Marsh SGE, Albert ED, Bodmer WF, et al. HLA Nomenclature. HLA Alleles website. Updated January 11, 2024. Accessed January 26, 2024. https://hla.alleles.org/nomenclature/index.html

HEMATOPOIETIC PROGENITOR CELL ENGRAFTMENT MONITORING

HSC.38120 Hematopoietic Progenitor Cell Engraftment **Phase II**

For hematopoietic progenitor cell engraftment, the polymorphic nature and independent segregation (eg, location on separate chromosomes) of the DNA system used is detailed and recorded in the literature.

REFERENCES

1) Clark JR, Scott SD, Jack AL, et al. Monitoring of chimerism following allogeneic haematopoietic stem cell transplantation (HSCT): Technical recommendations for the use of short tandem repeat (STR) based techniques, on behalf of the United Kingdom National External Quality Assessment Service for Leucocyte Immunophenotyping Chimerism Working Group. *Br J Haematol.* 2015;168(1):26-37.

HSC.38130 Chimerism **Phase II**

There are records of the accuracy of quantitative methods used to measure chimerism.

NOTE: The accuracy of quantitative methods used to measure chimerism must be verified at least annually by controlled blood mixing or other suitable method. If results on cell subpopulations are reported, there must be records of periodic testing of the purity of such cell subsets.

HSC.38140 Negative Control **Phase II**

A negative control is used and evaluated for non-specific background with each run.

REFERENCES

1) Clark JR, Scott SD, Jack AL, et al. (2015), Monitoring of chimerism following allogeneic haematopoietic stem cell transplantation (HSCT): Technical recommendations for the use of Short Tandem Repeat (STR) based techniques, on behalf of the United Kingdom National External Quality Assessment Service for Leucocyte Immunophenotyping Chimerism Working Group. *Br J Haematol.* 2015;168:26-37.

HSC.38150 Sensitivity Control **Phase II**

A sensitivity control is used and evaluated with each run.

NOTE: A low positive control may be used to meet this requirement.

HSC.38171 Internal Controls **Phase II**