

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