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**

For hematopoietic progenitor cell engraftment assays, internal controls are used to determine appropriate genotypes or at least to distinguish patient from donor(s) with each run.

NOTE: There must be criteria for the acceptance and rejection of the amplification of a particular genetic locus or individual sample.

HSC.38180 Preferential Amplification **Phase II**

Reactions are optimized to avoid preferential amplification. The minimum amount of DNA is determined to obtain optimal sensitivity.

NOTE: Method validation must include a dilution study to evaluate the concentration of DNA to determine minimum sensitivity of the assay.

HSC.38190 Cell Subset Purity **Phase II**

If cell subset enrichment is performed, the patient report includes the actual or approximate purity of the cell subset.

NOTE: The determination of the actual or approximate purity of the cell subset does not imply that the purity determined in validation studies can be used without further evaluation. An actual measurement may be performed at the time of sample testing. Some isolation methods and cell subpopulations (eg, CD56) may not produce enough cells to test purity and run the monitoring engraftment test. At a minimum, the purity can be determined for each lot of reagent used to isolate the cell subset and then be reported as an approximate purity for that specific lot.

HSC.38200 Hematopoietic Progenitor Cell Engraftment Testing **Phase II**

For hematopoietic progenitor cell engraftment, samples from pre-transplant patient (recipient), pre-transplant donor(s), post-transplant patient, and an appropriate control are analyzed concurrently.

NOTE: Previously generated data from pre-transplant specimens may be used to compare to post-transplant results if a validated system is used to identify and link the appropriate data files for concurrent analysis.

Evidence of Compliance:
- ✓ Records of HPC testing

HSC.38205 Engraftment Analysis **Phase II**

Prior to evaluating post engraftment specimens, the laboratory evaluates a specimen from the donor(s) and a pre-transplant specimen from the patient to determine the number of informative loci to test in order to meet the minimum number of loci needed for calculations.

Evidence of Compliance:
- ✓ Records of hematopoietic progenitor cell engraftment testing

HSC.38208 Preferential Allele Amplification **Phase II**

Preferential allele amplification is considered in the interpretation of hematopoietic progenitor cell engraftment tests.

HSC.38220 Minimal Number of Informative Loci **Phase II**