



For hematopoietic progenitor cell engraftment testing, a minimum of three informative loci are routinely used in the calculations.

NOTE: There are exceptions to this rule. Informative loci refer to loci that can distinguish between donor(s) and recipient. An exception for the number of informative loci used may occur in syngeneic twins (donor(s) and recipient) and rarely in closely related donor(s) and recipient.

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HSC.38658 Result Reporting

Phase II

For hematopoietic progenitor cell engraftment, the final report includes an appropriate summary of the methods, the loci tested, the number of informative loci used, the percent donor cells, an indication of any trace cells, and the sensitivity of the assay.

NOTE: For hematopoietic progenitor cell engraftment, when performing testing by next generation sequencing (NGS), the loci tested are not required to be listed on the report.

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.
- 2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

ADDITIONAL MOLECULAR TESTING METHODS

HSC.38690 ABO and RhD Typing by Molecular Methods

Phase II



ABO and RhD typing performed by molecular methods is used for presumptive ABO and RhD typing only. Donor-recipient ABO and RhD typing for transfusion and transplant compatibility evaluations is performed using FDA-cleared or approved serologic methods.

*NOTE: Transplant donor registries often collect samples from potential donors using buccal swabs or saliva. These samples cannot be used for traditional serological ABO/RhD blood group typing because fresh intact red blood cells (RBCs) are not available. Molecular ABO and RhD typing may be performed to predict the presumptive ABO and RhD phenotype to aid in finding an appropriate donor. Because the ABO and Rh genes are complex, prediction of ABO and Rh phenotype by molecular methods is currently used in immunohematology red cell reference laboratories that focus on blood typing complications, for research, or for providing **preliminary** information that can be confirmed by FDA-cleared or approved methods.*

The use of molecular based screening assays is not acceptable for ABO and RhD blood type assignment for the purposes of transfusion or transplantation. ABO and RhD typing by FDA-cleared or approved serologic methods must be used for the purpose of transfusion or donor and recipient ABO and RhD typing for transplantation.

Evidence of Compliance:

- ✓ Donor-recipient compatibility records with serologic ABO and RhD typing results