HLA CLASS I AND II ANTIGEN TYPING

Inspector Instructions:

READ	• Sampling of HLA Class I & Class II Ag typing policies and procedures. Procedures should specify the level of resolution of HLA typing required for each tissue or organ transplanted. • Sampling of HLA typing of solid organ and hematopoietic progenitor cell transplantation policies and procedures • List of antigens defined by reagents used • Sampling of typing reagent validation records • Sampling of typing tray QC records
ASK	• How does your laboratory select target cells to ensure the detection of antigens recognized by the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System? • What is your laboratory's course of action when a donor cannot be reliably HLA typed?

HSC.28186 Serologic Typing - Class I **Phase II**

Target cells are defined for serological determination of HLA Class I antigens, and selected to permit typing the antigens officially recognized by the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System for which reagents are readily available.

NOTE: HLA Typing for all hematopoietic progenitor cell donors and recipients, and deceased organ donors must be performed by molecular methods. Serological determination of HLA Class I antigens should be performed on T cells or mononuclear cell preparations. Local serological typing reagents must be supported by appropriate documentation of HLA specificity, using cells of known HLA types. The test must detect WHO recognized specificities.

REFERENCES
1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1278(b)].

HSC.28373 Serologic Typing - Class II **Phase II**

The methodology for serological Class II antigen typing defines the proportion of B-cells needed for optimal testing, and the specificities that are officially recognized by the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System and for which reagents are readily available.

NOTE: The method should produce at least 80% B-cell enriched preparations. Documentation of B cell enrichment may not be necessary when procedural techniques already distinguish T- and B-lymphocytes, or when well-characterized antibodies are used that can only discriminate and identify Class II antigens. HLA typing for all hematopoietic progenitor cell donors and recipients, and deceased organ donors must be performed by molecular methods.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1278(b)].
2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.