HSC.28560   Class I Antigen Defined   **Phase II**

The minimum number of Class I antisera used are defined by the laboratory.

HSC.28747   Class II Antigen Defined   **Phase II**

The minimum number of Class II antisera used is defined by the laboratory.

HSC.28934   Typing Trays   **Phase I**

The typing trays used for disease association testing permit characterization of at least those antigens accepted by the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System for which sera are readily available.

REFERENCES
1)   Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7170 [42CFR493. 1278(a) through (c)]

HSC.28996   Controls - Typing Trays   **Phase II**

Each typing tray contains both a positive and a negative control.

NOTE: The positive control must be known to react with all cells expressing the class of antigens being tested at a titer comparable with the typing reagents. Each typing tray must also contain one negative control. Cell viability in the negative control must be sufficient to accurately interpret the results. The use of sufficiently discriminatory positive and negative controls also applies to assays in which cell viability is not required.

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(a)(3)].

CYTOTOXICITY CROSSMATCH

Inspector Instructions:

READ

- Sampling of cytotoxicity crossmatch policies and procedures including method sensitivity

HSC.29308   HLA Crossmatch Sensitivity   **Phase II**

The method used in the HLA crossmatch procedure is more sensitive than the basic complement dependent micro-lymphocytotoxicity crossmatch and is able to distinguish between reactions with T and B lymphocytes, such that crossmatches with donor T-lymphocytes identify Class I anti-HLA antibodies and crossmatches with donor B-lymphocytes identify Class I and Class II anti-HLA antibodies.

Evidence of Compliance:
✓   Records of method sensitivity **AND**
✓   Peer-reviewed published literature on method sensitivity