Histocompatibility

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Standard	***Guidance***
Histocompatibility Standard of Practice 1 (HC S1): Test Procedure In addition to the requirements in Test Procedure Content Standard of Practice 1, the laboratory must have a standard operating procedure that includes, as applicable, the policy for antigen and allele definition and typing, including the updating of results and issuance of amended reports.	
Histocompatibility Standard of Practice 2 (HC S2): Human Leukocyte Antigen Typing The laboratory must, as applicable: a) when using immunologic reagents to facilitate or enhance the isolation or identification of lymphocytes or lymphocyte subsets, monitor the efficacy of the methods by the use of appropriate quality control procedures; b) use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O) Committee on nomenclature.	

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Histocompatibility Standard of Practice 3 (HC S3): Human Leukocyte Antigen Antibody Screening and Identification The laboratory must, as applicable, make a reasonable attempt to have available monthly serum specimens for all potential transplant beneficiaries for periodic antibody screening and crossmatching.	
Histocompatibility Standard of Practice 4 (HC S4): Transplantation If a laboratory provides histocompatibility testing for infusion and transplantation, the laboratory must: a) have and follow policies and protocols specifying the histocompatibility testing (i.e., HLA typing, antibody screening and identification, crossmatching) to be performed for each type of cell, tissue or organs to be infused or transplanted, as applicable: i. testing protocols for deceased donor, living, paired, and combined organ transplants; ii. testing protocols for patients at high risk for allograft rejection vs. unsensitized; and iii. type and frequency of testing required to support clinical transplant protocols; b) have a process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant. If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.	

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Histocompatibility Standard of Practice 5 (HC S5): Crossmatching The laboratory must, as applicable: a) Establish and follow written policies and procedures for performing a crossmatch. b) Have available and follow written criteria for the following: i. Defining donor and recipient HLA antigens, alleles, and antibodies to be tested; ii. Defining the criteria necessary to assess a recipient's alloantibody status; iii. Assessing recipient antibody presence or absence on an ongoing basis; iv. Typing the donor, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable; v. Describing the circumstances in which pre- and post- transplant confirmation testing of donor and recipient specimens is required; vi. Making available all applicable donor and recipient test results to the transplant team; vii. Ensuring immunologic assessments are based on test results obtained from a	

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test report from a CLIA- certified laboratory; viii. Defining time limits between recipient testing and the performance of a crossmatch. c) The test report must specify the type of crossmatch performed.	
Histocompatibility Standard of Practice 6 (HC S6): Environmental Temperature Monitoring The laboratory must have policies for the monitoring of refrigerators and freezers to ensure storage temperatures are maintained for each type of specimen (donor and recipient) and reagent that includes: a) use a continuous monitoring and alert system to monitor storage temperatures; b) have a documented plan for alternative storage for an emergency or a refrigerator or freezer failure; and c) a system to easily retrieve specimens.	