Histocompatibility

Histocompatibility	
Former Standard and Guidance	***Revised Standard and 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: a) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the human leukocyte antigen (HLA) typing technique(s) performed; b) the preparation and/or selection of typing reagents, whether locally or commercially prepared; c) the policy for antigen redefinition and retyping, including, where applicable, the updating of results and issuance of amended reports; d) a protocol for ensuring that reagents used for typing are adequate to define all clinically relevant loci, at minimum, all HLA-A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available; and e) criteria for the assignment of HLA type.	**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.

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Histocompatibility Standard of Practice 2 (HC S2): Human Leukocyte Antigen Typing The laboratory must, as applicable: a) use a technique(s) that is established to optimally define, as applicable, human leukocyte antigen (HLA) Class I and II specificities; b) check each HLA typing by testing at minimum: i. a positive control; ii. a negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results: a. in assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results; iii. positive control materials for specific cell types when applicable (T cells, B cells, and monocytes); c) if the laboratory uses immunologic reagents (e.g. antibodies, antibody-coated beads) to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures; d) if reagent typing sera is prepared in-house, the	**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.

inventory must indicate the source, bleeding date, identification number, reagent specificity and volume remaining; e) use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O) Committee on nomenclature; potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.	

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Histocompatibility Standard of Practice 3 (HC S3): Human Leukocyte Antigen Antibody Screening The laboratory must, as applicable: a) use a technique that detects human leukocyte antigen (HLA) specific antibody with a specificity that is equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay; b) use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens; c) use a cell panel that contains all major HLA specificities and common splits or, if the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and d) check each antibody screening test using, at minimum: i. a positive control material containing antibodies of the appropriate isotype for the assay; and ii. a negative control material.	**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.
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Histocompatibility Standard of Practice 4 (HC S4): Transplantation If a laboratory provides histocompatibility testing for a transplantation, the laboratory must, as applicable: a) HLA type all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection; b) HLA type cells from organ donors referred to the laboratory; c) have available and follow a written policy that requires screening potential transplant recipients for preformed HLA-specific antibodies at a frequency consistent with clinical transplant protocols; d) have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol; e) have and follow policies and protocols specifying the histocompatibility testing (i.e., HLA typing, antibody screening, crossmatching) to be performed for each type of cell, tissue or organs to be transfused or transplanted with policies that must include, as applicable: i. testing protocols for deceased donor, living, and combined organ transplants; ***ii.*** testing protocols for patients at high risk for allograft rejection; and	**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.

iii. the level of testing required to support clinical transplant protocols (e.g., antigen or allele- level typing); f) for renal transplantation and combined organ transplant in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted. **Guidance –** a) The laboratory should make a reasonable attempt to have available monthly serum specimens for all potential transplant beneficiaries for periodic antibody screening and crossmatching.	
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Former Standard and Guidance	***Revised Standard and Guidance***
Histocompatibility Standard of Practice 5 (HC S5): Crossmatching The laboratory must, as applicable: a) use a technique(s) documented to have increased sensitivity in comparison with the basic complement- dependent microlymphocytotoxicity assay; b) have available and follow written criteria for: i. selecting appropriate patient serum samples for crossmatching; ii. the preparation of donor cells or cellular extracts as applicable to the crossmatching techniques performed; and	**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;

c) *select appropriate controls to monitor the test system to ensure acceptable performance.*	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 test report from a CLIA- certified laboratory; and viii. Defining time limits between recipient testing and the performance of a crossmatch. c) The test report must specify the type of crossmatch performed.

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Histocompatibility Standard of Practice 6 (HC S6): Environmental Temperature Monitoring Refrigerators and freezers must be monitored to ensure storage temperatures are maintained for each type of specimen (donor and recipient) and reagent. The laboratory must: a) use a central or audible temperature alarm 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.	**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.