Histocompatibility

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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.	

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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 inventory must indicate the source, bleeding date,	

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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.	
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.	

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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	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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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.	
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 c) select appropriate controls to monitor the test system to ensure acceptable performance.	
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:	

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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.	