

D HLA Typing

D1.000 The laboratory must be able to define HLA-A,-B, -Bw4,Bw6, -C, -DR and -DQ antigens at a level that is appropriate for solid organ transplantation.

D1.100 Laboratories performing HLA typing using cytotoxicity techniques must conform to all pertinent standards in Section H- Cytotoxicity Methods.

D1.200 Laboratories performing HLA typing using nucleic acid analysis must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

D1.300 If alternative methods are used for HLA typing, procedures must be defined and validated, and must include sufficient controls to ensure accurate assignment of types. All relevant standards from the above sections must be applied.

D2.000 Typing Assignment

D2.100 Each HLA antigen must be defined by a sufficient number of reagents to clearly define each antigen or allele group for which the laboratory tests.

D2.200 The level of resolution of HLA typing must be appropriate for the clinical application.

D2.300 The method of assignment of HLA phenotypes must be documented for each technique used.

D2.400 The laboratory must have and adhere to a written policy that establishes when antigen redefinition and retyping are required.

D2.500 The laboratory must maintain a list of antigens and/or alleles defined by each test used in the laboratory.

D3.000 Reagent Validation

D3.100 Cell or DNA panels of known HLA class I and class II phenotype must be available to validate new typing reagents.

D3.200 The specificity of typing reagents obtained locally or from other sources and used for preparation of local trays must be documented and confirmed by external and/or internal QC testing.

D3.300 Each lot and/or shipment of new commercial reagents must be evaluated. The laboratory must establish and employ detailed policies and procedures for such evaluations. ~~Each new lot must be evaluated by testing either with at least five different known phenotypes or in parallel with previously evaluated reagents.~~

NOTE: D3.300 - Effective pending notice to the membership.

D3.400 Techniques used must be validated to optimally define HLA class I and/or class II antigens and/or alleles.

D4.000 HLA Typing by Nucleic Acid Analysis

D4.100 The HLA alleles detected by each primer, probe or template primer combination must be defined. Primers and probes must be tested with all alleles that are recognized by the W.H.O. Nomenclature Committee for Factors of the HLA System, provided that nucleotide sequences and reference DNA are readily available.

D4.200 The laboratory must have a process to recognize and document ambiguous combination(s) of alleles for each template/primer or probe combination.

D4.300 Typing by Sequenced Based Typing (SBT)

D4.310 Templates must have sufficient specificity for a locus or allele to provide interpretable primary sequencing data.

D4.320 Each unknown sequence must be compared with the sequences of all alleles that are recognized by the W.H.O. Nomenclature Committee for Factors of the HLA System provided that the nucleotide sequences are readily available.

D4.330 The laboratory must maintain records that define the sequence database utilized to interpret the primary data. This database must be updated at least annually. If a determined sequence is ambiguous (i.e., more than one possible interpretation of available data) the report must indicate all possible allele combinations.