

Standards for Histocompatibility Testing

Notice and Disclaimer

These standards set forth only the minimum requirements for accredited histocompatibility laboratories. These standards do not set forth all that may be required of a facility to conform to federal or state laws or regulations (or non US equivalent) or the standard of care prevailing in the relevant community. Each facility must determine whether additional practices and procedures should be used in their particular locale. UNOS expressly disclaims any warranty that compliance with these standards meets all federal or state laws or regulations (or non US equivalent) or the standard of care that may prevail in any relevant community.

- A General Policies
- B Personnel Qualifications
- C Quality Assurance
- D HLA Antigens/Alleles
- E HLA Typing
- F Mixed Leukocyte Culture Tests
- G Antibody Screening
- H Renal and Pancreas Organ Transplantation
- I Other Organ Transplantation
- J Red Cell Typing for Organ Transplantation
- K Immune Function/Response Monitoring
- L Chimerism Analysis
- M Nucleic Acid Analysis
- N Flow Cytometry
- O Enzyme Linked Immuno Sorbent Assay (ELISA)

D- HLA Antigens/Alleles

D1.000 Nomenclature

D1.100 Terminology of HLA antigens/alleles must conform to the latest report of the W.H.O. Nomenclature Committee for Factors of the HLA System (W.H.O. Committee).

D1.200 Potential new antigens/alleles not yet approved by the W.H.O. Committee must have a local designation that cannot be confused with W.H.O. terminology.

D1.300 Phenotypes and genotypes must be expressed as recommended by the most recent W.H.O. Nomenclature Report. The locus designation must always be included.

D1.400 If only a single antigen/allele is found at a locus, the reported typing must not include it twice unless homozygosity is proven by family studies or other methods. Conversely, a confirmed "blank antigen" ('X') can only be assigned if proven by family studies or other methods.

D2.000 Determination of Haplotypes and Genotypes

D2.100 Family studies

D2.110 Family studies are required for definitive assignment of haplotypes and genotypes

D2.200 Genotype reports must include haplotype assignments and an explanation of recombination if this occurs.

D2.200 Unrelated individuals and incomplete family studies.

D2.210 If probable haplotypes are assigned, given the phenotype, this must be determined from the known haplotype frequencies in the relevant population.

D2.220 The haplotype frequencies used must be from the most complete and reliable studies available.

D2.230 The haplotype frequencies used must be those most appropriate for the ethnic group of the subject.

D2.240 Reports of probable haplotypes based on population frequencies must clearly indicate that they were so derived.