

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)

L- Chimerism Analysis

L1.000 Sample Processing

L1.100 The laboratory must have written procedures for processing of the donor sample and the patient's pre- and post-transplant samples.

L1.200 If the methods used in sample processing differ depending on the clinical indication, the laboratory must have written directions to identify the type of request and to specify the processing methods; and must document that the appropriate procedure was followed.

L1.300 If sample processing involves the isolation of cell subsets or specific hematopoietic cell lineages, the laboratory must document the purity obtained, unless sample is insufficient. If purity is not documented for a given sample, then this must be documented on the patient report.

L2.000 Nucleic Acid Analysis

L2.010 Laboratories performing engraftment and chimerism testing using nucleic acid analysis must conform to all pertinent standards in Section M- Nucleic Acid Analysis and all Standards in this section, as applicable.

L2.100 Tests using Restriction Fragment Length Polymorphism (RFLP)

L2.110 Sample Requirements

L2.111 The method used to prepare DNA must provide sufficient quality and quantity for analysis. Written guidelines must specify the minimal acceptable sample in terms of volume or numbers of nucleated cells.

L2.200 Tests Using Amplification-Based Techniques

L2.210 Nucleic acids must be prepared by a method that has been validated in the laboratory to provide sufficient quantity and quality of DNA for testing specimens containing the number of cells in test samples.

L2.220 Primers

L2.221 It is recommended that primers be available for testing for a sufficient number of polymorphic genetic loci to identify informative recipient and donor markers among all individuals tested, except monozygotic twins.

L2.222 The specificity and sequence of primers must be defined. The genetic designation (e.g., locus) of the target amplified by each set of primers must be defined and documented. For each locus analyzed, the laboratory must have documentation that includes the chromosome location, the approximate number of known alleles, and the distinguishing characteristics (e.g., sizes, sequences) of the alleles that are amplified.

L2.223 Primers must be used under empirically determined conditions that achieve the defined sensitivity and specificity of amplification. The amplification conditions must be demonstrated by the laboratory to achieve the defined sensitivity and specificity and must yield an adequate quantity of specific product with minimal amplification of non-specific fragments.

L2.224 Each lot of primer must be tested for specificity and product quantity using reference templates under routine conditions and must be retested periodically.

L2.230 Controls

L2.231 For each locus tested, patient and donor samples collected pre-transplant, and/or control samples demonstrated to have similar performance characteristics (e.g., sensitivity, competition in PCR) must be amplified and analyzed concurrently with patient samples collected post-transplant. It is recommended that known mixtures of donor and recipient be amplified and analyzed concurrently with patient samples collected post-transplant.

L2.232 Each test must include internal controls, for the characteristic (e.g., size, sequence polymorphism) used, to distinguish donor and recipient alleles.

L2.400 Amplified Product and Detection

L2.241 Criteria for accepting or rejecting the amplification of a particular genetic locus or of an individual sample must be specified.

L2.242 Optimal electrophoretic conditions must be empirically determined for each genetic locus, acceptable limits established and their use documented.

L2.250 Analysis and Reports

L2.251 Potential for preferential amplification of different sized alleles must be assessed and considered in the analysis.

L2.252 If more than one locus is amplified in a single amplification (multiplex), the effects of such amplification on each system must be assessed and considered in the analysis.

L2.253 Reports must identify the genetic loci analyzed according to standard nomenclature or published reference. For RFLP testing, the restriction endonuclease used and the fragment size must be identified.

L2.254 If results are reported in a quantitative or semi-quantitative manner, criteria for evaluating the relative amounts of recipient and donor in a mixed chimeric sample must be established.

L2.255 It is recommended that when mixed chimerism is not detected, reports state the level of sensitivity for each locus tested.