

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)

F- Mixed Leukocyte Culture Tests

F1.000 Techniques

F1.100 At the start of culture, lymphocyte viability must be documented and must be sufficient to maintain cell proliferation to ensure accurate test results

F1.200 Serum used in the culture medium must be screened to ensure its ability to support cellular proliferation, must be lacking cytotoxic antibodies and must be sterile.

F1.300 MLC cultures must be incubated for the length of time shown to give appropriate cellular proliferation.

F1.400 The negative control for each responder cell must consist of responder cells stimulated with autologous cells.

F1.500 Each assay must include HLA class II disparate stimulator cells as a positive control for responder cell proliferation.

F1.600 In each MLC test, stimulator cells must be shown to be capable of stimulating unrelated HLA class II disparate cells.