

## 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)

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### A- General Policies

A1.000 These Standards have been prepared by the UNOS Histocompatibility Committee based on the most recent Standards prepared by the Committee on Quality Assurance and Standards of the American Society For Histocompatibility and Immunogenetics (ASHI) and provisions of the final rules of the Clinical Laboratory Improvement Act of 1988 (CLIA '88), and have been approved by the UNOS Board of Directors

A2.000 These Standards have been established for the purpose of ensuring accurate and dependable histocompatibility and transplantation testing consistent with the current state of technological procedures and the availability of reagents.

A3.000 These Standards establish minimal criteria that all histocompatibility laboratories must meet if their services are to be considered acceptable.

A4.000 Certain Standards are obligatory. In these instances, the Standards use the word "must." Some Standards are highly recommended but not absolutely mandatory. In these instances the Standards use words like "may" or "it is recommended that".

A5.000 Procedures to be used in histocompatibility testing often have multiple acceptable variations. The accuracy and dependability of each procedure must be validated in each laboratory. Use of the latest edition of the ASHI Laboratory Procedure Manual is highly recommended as a reference procedure manual for all laboratories.

A6.000 Some procedures have sufficient documentation of effectiveness to warrant their use in clinical service even though they are not available in or obligatory for all laboratories.

A7.000 Laboratories using the name of UNOS as certification of compliance to these Standards must be laboratories that have been approved by UNOS.

A8.000 If histocompatibility or transplantation tests not covered by UNOS Standards are performed, the laboratory must have validated the test procedures. There must be documented expertise and accreditation, if available, for those tests and participation in external Proficiency Testing if available, or there must be other procedures to validate performance at least semi-annually.