

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)

B- Personnel Qualifications

B1.000 Consistent with current Clinical Laboratory Improvement Act (CLIA) regulations, the laboratory must have a Director, a Technical Supervisor, and a Clinical Consultant. When the appropriate criteria are met as defined by CLIA '88, one individual may serve in 1, 2 or all 3 capacities, i.e., Laboratory Director, Technical Supervisor and Clinical Consultant.

B2.000 A Director/Technical Supervisor must hold an earned doctoral degree in a biologic science, or be a physician, and subsequent to graduation must have had four years experience in immunology or cell biology, two of which were devoted to formal training in human histocompatibility testing. Credit toward these two years can be applied at the rate of 0.4 years for each year of appropriate working experience in human histocompatibility testing. The Director must have documentation of professional competence in the appropriate activities in which the laboratory is engaged. This must be based on a sound knowledge of the fundamentals of immunology, genetics and histocompatibility testing and reflected by external measures such as participation in national or international workshops and publications in peer-reviewed journals He/she is available on site commensurate with the workload at the laboratory, provides adequate supervision of technical personnel, utilizes his/her special scientific skills in developing new procedures and is held responsible for the proper performance, interpretation and reporting of all laboratory procedures and the laboratory's successful participation in proficiency testing.

B3.000 A General Supervisor must hold a bachelor's degree and have had three years' experience in human histocompatibility and/or transplantation immunology testing under the supervision of a qualified Director/Technical Supervisor or must have five years of supervised experience and an appropriate associate's degree or certificate, as required by the final rules of the Clinical Laboratory Improvement Act (CLIA '88), if a bachelor's degree has not been earned. CHS (ABHI) certification is highly recommended.

B4.000 A Histocompatibility Technologist must meet the qualifications for a Histocompatibility Technologist as defined by CLIA '88 and must have had one year of supervised experience in human histocompatibility and/or transplantation immunology testing, regardless of academic degree or other training and experience. It is highly recommended that Histocompatibility Technologists be either CHS or CHT (ABHI) certified. The term

Histocompatibility Technician is applied to trainees and other laboratory personnel with less than one year's supervised experience in human histocompatibility and/or transplantation immunology testing, regardless of academic degree or other training and experience.

B5.000 The size of the staff must be large enough to carry out the volume and variety of tests required without a degree of pressure that will result in errors.

B6.000 All personnel must be licensed or meet the standards required by Federal, State and local laws.

B7.000 A Clinical Consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the appropriateness of human histocompatibility and/or transplantation immunology tests ordered and the interpretation of test results in relation to patient diagnosis and management. A Clinical Consultant must comply with the personnel qualifications set forth in the final version of the Clinical Laboratory Improvement Act (CLIA '88) Regulations.