

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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01.000 Instrument Standardization/Calibration

01.100 The ELISA Reader

01.110 The light source and filter must produce the intensity and wavelength of light required for the test system.

01.120 Calibration/verification of plate alignment and instrument linearity must be performed according to the manufacturer's instructions or at least once every 6 months and must be documented.

01.200 If used, microplate washer performance must be checked monthly and acceptable performance must be documented.

02.000 ELISA Technique

02.100 If commercial kits are used, the manufacturer's instructions must be followed unless the laboratory has performed and documented testing to support a deviation in technique or analysis.

02.110 Each assay must contain positive, negative and reagent controls that are appropriate for the intended use of the assay and the test results. The dilution of reagents and test specimens must be documented.

02.120 For an assay to be valid it must be documented that all controls meet or exceed established thresholds as specified in the assay procedure.

02.130 There must be a documented system in place for identifying which lots of reagents were used for an assay.

02.140 Prior to reporting results obtained with new lots or shipments of reagents, satisfactory performance must be verified and documented.

O2.150 Sample identity and proper plate orientation must be maintained throughout the procedure.