

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)

J- Red Cell Typing For Organ Transplantation

J1.000 Determination of ABO Group and Rh Type

J1.100 ABO group must be determined by testing red blood cells using anti-A and anti-B sera, and by testing the serum or plasma for expected antibodies with A1 and B cells. (Cord cells and blood from newborns must be tested for red cell antigens only, not for antibodies).

J1.110 Discrepancies between cell and serum groups must be resolved before ABO group is assigned.

J1.120 If testing for the A₁ subgroup of ABO group A is performed, the extract of *Dolichos biflorus* must be used at a dilution and with a technique documented not to agglutinate A₂ cells. Each assay or batch test run must include known A₁ and A₂ cells as controls.

J1.130 If titration of anti-ABO antibodies is performed, the procedure and criteria for interpretation must be established and validated by the laboratory.

J2.200 If Rh typing is performed, the Rh type must be determined using anti-D. A control system, appropriate to the anti-D reagent in use, must be used.

J2.300 Reagents

J2.310 Reagent typing sera (anti-A, anti-B and anti-D) must meet or exceed appropriate FDA criteria. A1 cells and B cells may be prepared by the facility provided there is documentation that they are satisfactory for the intended use.

J2.320 Testing must be performed according to reagent manufacturers' instructions.

J2.330 All reagents must be shown to be reactive and specific on the day of use by the method employed.

J2.400 There must be a comparison of the current ABO group with previous records that are readily available. Any discrepancy found between the current results and the previous record must be resolved before transplantation.

J2.500 Red cell testing records must be maintained for 5 years or for the interval required by local, state or federal standards.