

## 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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## G- Antibody Screening

### G1.000 Techniques and Reagents

#### G1.100 Techniques

G1.110 Antibody specific for HLA antigens must be identified by complement-dependent cytotoxicity techniques or by other techniques that have been demonstrated by the laboratory, or established in publications, to identify HLA-specific antibody (ies) with a specificity equivalent or superior to that of the NIH/basic microlymphocytotoxicity technique, as appropriate for the clinical indication. It is recommended that the screening process be predictive of crossmatch results.

G1.120 To detect antibodies to HLA Class II antigens, a method must be used that distinguishes them from antibodies to HLA class I antigens.

G1.130 There must be a procedure to monitor and adjust for non-specific binding of antibody.

G1.140 Additional techniques, such as those that detect cellular sensitization or antibodies that are lymphocyte-dependent or non-HLA specific (e.g., those using monocytes or cells from specific tissues), may be used to supplement the laboratory's technique that meets the requirements of G1.110. These techniques must use appropriate panel reagents and controls.

#### G1.200 Sera

G1.210 Sera must be tested at a concentration(s) determined to be optimal for detection of antibody(ies) to HLA antigens. The dilution(s) must be documented in the test records.

G1.220 Negative control sera must include a human serum demonstrated to be non-reactive in the assay used. Each assay must include negative control(s).

G1.230 Each assay must include a positive control. It is recommended that the positive control be a human serum documented to react with the intended target antigens. The antibodies must be of the appropriate isotype and specificity for each assay.

### **G1.300 Panel and Target Selection**

G1.310 The panel of antigens must be sufficient in number and phenotypic distribution with respect to individual antigens and/or crossreactive groups (CREGs) for the population served and for the intended use of the test results. The laboratory must document the method used to define CREGs.

G1.320 For assays intended to provide information on HLA antibody specificity, documentation of the HLA Class I and/or Class II phenotypes of the panel must be maintained.

### **G2.000 Antibody Screening by Complement-Dependent Cytotoxicity**

#### **G2.100 Target Cells**

G2.110 To detect antibodies to HLA Class I antigens, target cells may be mononuclear cells from peripheral blood, lymph nodes or spleen or may be cell lines or CLL cells.

G2.120 To detect antibodies to HLA Class II antigens, B-lymphocytes, B-lymphoblastoid cell lines or CLL cells may be used.

### **G3.000 Antibody Screening by Flow Cytometry**

G3.100 Laboratories performing assays using flow cytometry must conform to the Standards in Section N1.000 Instrument Standardization/Calibration and in Section N2.000 Flow Cytometric Crossmatch Technique.

### **G4.000 Antibody Screening by ELISA**

G4.100 Laboratories using ELISA techniques for antibody screening must conform to Standards in Sections O- Enzyme Linked Immuno Sorbent Assay (ELISA).

G4.200 The validity of changing cutoff points to increase sensitivity of the ELISA assay must be documented with well-characterized HLA antibodies titrated to their endpoint.