

## 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.

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- B Personnel Qualifications
- C Quality Assurance
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- 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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### H- Renal and Pancreas Organ Transplantation

H1.000 If deceased donor transplants are performed, personnel for the required histocompatibility testing must be available 24 hours a day, seven days a week.

H2.000 Laboratories must have a documented policy in place to evaluate the extent of sensitization of each patient at the time of initial evaluation and following potentially sensitizing events. This is recommended to include policies for detection and consideration of antibodies that are present that may not be detrimental to graft survival such as autoantibodies or DTT or DTE reducible antibodies.

H2.100 Laboratories must have a program to periodically screen serum samples from each patient for antibody to HLA antigens. The laboratory must have a documented policy establishing the frequency of screening serum samples and must have data to support this policy. It is recommended that samples be collected monthly.

H2.200 Laboratories must have a policy to obtain and maintain a record of potentially sensitizing events for each patient and to obtain and store serum samples after each of these events. It is recommended that serum samples be tested for antibody to HLA antigens and that 1) information about antibody specificity be considered when evaluating the patient for transplant or 2) the serum sample be used in crossmatch tests.

H2.300 It is recommended that the HLA class I and class II specificity of antibodies be identified and reported and be distinguished from antibodies to other antigens.

### H3.000 Crossmatching

~~H3.100-Crossmatches are not mandatory for all kidney and pancreas transplant candidates. For example, patients documented as historically unsensitized, and who have no intervening sensitizing events, may be transplanted without a final crossmatch. However, laboratories must perform a prospective crossmatch if so requested by the transplant center and dictated by clinical circumstances. The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals. Histocompatibility~~

laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies.

*NOTE: The amendments to By-Laws, Appendix B, Attachment 1, (H3.100 – Crossmatching) shall be effective January 1, 2005.*

### **H3.200 Techniques**

H3.210 Crossmatching must use techniques documented to have increased sensitivity in comparison with the basic/NIH complement-dependent microlymphocytotoxicity test.

H3.220 Crossmatches must be performed with potential donor T lymphocytes. It is recommended that crossmatches be performed with B lymphocytes using a method that distinguishes between reactions with T and reactions with B lymphocytes.

H3.230 The laboratory must have and adhere to a policy determining the serum(a) used in the final crossmatch. The efficacy of the policy must be supported by published data or data generated in the laboratory. The policy must include selection of sera for allosensitized patients that addresses the impact of historic and current sensitizing events. It is recommended that a serum collected within 48 hours of transplant be used for crossmatching of allosensitized patients as well as patients with a recent sensitizing event.

### **H3.300 Samples**

H3.310 Sera must be tested at a dilution that is optimal for each assay. For lymphocytotoxicity crossmatches, sera must be tested undiluted and may also be tested at one or more dilutions.

H3.400 The laboratory must have a policy for storage and maintenance of recipient sera. The policy must define the samples to be retained and the duration of storage.

### **H4.000 HLA Typing**

H4.100 Prospective typing of donors and recipients for HLA-A, B, Bw4, Bw6, and DR antigens is mandatory.

H4.200 Prospective typing of donors and recipients for HLA-C, and DQ antigens and for DR51, DR52, DR53, is highly recommended.

### **H5000 Deceased Donors**

H5100 Donors may be typed using lymphocytes from lymph nodes, spleen or peripheral blood. It is recommended that, whenever possible, preprocurement samples be used for typing and screening crossmatches.