

## **Proposed 2011 new ASHI Standards**

(Includes relevant section of existing standards for reference.)

### **D.5.3.2.2 Laboratories performing testing for renal and/or pancreas transplantation from deceased donors must also:**

**D.5.3.2.2.1** Prospectively type donor and transplant candidate for HLA-Bw4/w6.

**D.5.3.2.2.2** Follow policies and procedures established by a joint agreement with the transplant program to have periodic (e.g. monthly) serum samples submitted from potential transplant recipients for HLA antibody screening and crossmatching.

**D.5.3.2.2.3** Have results of final crossmatches available before renal transplantation or combined organ and tissue transplants in which a kidney is to be transplanted, except for emergency situations. If emergency transplants are performed before the crossmatch test results are available, information provided by the transplant candidate's physician to the laboratory as to the reason for the emergency transplant must be documented.

**D.5.3.2.2.4** All UNOS histocompatibility laboratories must review and verify the UNet Waitlist histocompatibility data for each patient for whom the laboratory performed testing. Documentation of such review must be kept for at least three years or the interval required by local, State and Federal regulations, whichever is the longer, and must be available for audit by UNOS.

**D.5.3.2.2.5** All UNOS histocompatibility laboratories must use a method for antibody identification that can identify HLA antibody specificities even in very highly sensitized transplant candidates. A solid phase method must be used if unacceptable antigens based on antibody screening are listed.

### **Proposed new: D.5.3.2.2.6**

**All UNOS histocompatibility laboratories prospectively typing all deceased donors for OPTN matchruns must use a molecular method to assign HLA-A,-B,-Bw4/w6,-C,-DR, -DR51/52/53 and -DQ at the antigen level of resolution needed to meet the most recent OPTN/UNOS tables of antigen and unacceptable antigen equivalencies.**

Guidance: Verify prospective molecular typing of donors for HLA-A,-B,-C,-DR, -DQ.

### **Proposed new D.5.3.2.2.7**

**All UNOS histocompatibility laboratories prospectively typing deceased donors for OPTN matchruns must distinguish common null alleles from expressed genes (antigens) as appropriate for solid organ allocation and transplantation.**

Guidance: Verify assignment of nulls alleles by laboratory protocols.  
(Common: A23-B\*44:03-CW\*04:09N, DR15-DR51N-DQ5, DR7-DR53N-DQ9)

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(Includes relevant section of existing standards for reference)

### **D.5.3.5 Transplantation of Other Organs and Tissues**

**D.5.3.5.1** If final crossmatches required by policies were not performed prospectively, the laboratory must document the circumstances, if known.

**D.5.3.5.2** Laboratories performing testing for transplantation other than renal and/or pancreas transplantation must follow policies and procedures established by a joint agreement with the transplant program to have serum samples submitted from potential transplant recipients for HLA antibody screening and crossmatching.

### **Proposed new D.5.3.5.3**

**All UNOS histocompatibility laboratories prospectively typing deceased donors for OPTN matchruns other than renal and/or pancreas transplantation must follow D.5.3.2.2.6 and D.5.3.2.2.7.**

Guidance: Not required by UNOS at this point but may be with current Thoracic proposals on the table to use CPRA and Unacceptable antigens.

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