

## **Criteria for Participating Testing Laboratories**

### **1.0 General**

- The laboratory must adhere to applicable federal, state, and local laws.

### **2.0 Accreditation**

- HLA Typing laboratories must be accredited by The American Society for Histocompatibility and Immunogenetics (ASHI), Centers for Medicare & Medicaid Services (CMS), The College of American Pathologists, the European Federation for Immunogenetics (EFI), or another non-U.S. equivalent.
- Laboratories testing for IDMs, ABO/Rh typing, testing for unexpected antibodies to red cell antigens, and other tests defined by international recommendations and regulations shall be certified by the Clinical Laboratory Improvement Amendments program (CLIA) and must comply with FDA regulations.
- Laboratories must conduct IDM tests using FDA-approved kits.

### **3.0 Responsibilities**

- The laboratory shall be responsible for maintaining the quality of testing.
- The laboratory shall provide CRIR with applicable up-to-date certificates of accreditation and may also provide certificates stating compliance with state laws, laboratory licenses, and other related documents.

### **4.0 Written Standards**

- The laboratory shall maintain written standards for all aspects of HLA typing and/or infectious disease testing.
- The laboratory shall provide documentation annually, at a minimum, demonstrating that they continue to meet these criteria. The laboratory must make available complete standard operating procedures upon request.