§493.1278 Standard: Histocompatibility

(f) Transplantation. Laboratories performing histocompatibility testing for transfusion and transplantation purposes must do the following:

> **(f)(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable--**
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> > **(f)(1)(i) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;**
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> > **(f)(1)(ii) Testing protocols for patients at high risk for allograft rejection; and**
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> > **(f)(1)(iii)The level of testing required to support clinical transplant protocols (for example, antigen or allele level).**

Interpretive **Guidelines §493.1278(f)**

In conjunction with the transplantation center the laboratory establishes written policies on the testing protocols it performs in support of the clinical transplant program. Policies should address when HLA testing and final crossmatches are required for patients that have demonstrated presensitization. For organs such as liver and heart (non-renal), it is not uncommon for laboratories to perform retrospective crossmatches if the patient demonstrates the absence of preformed antibodies by prior screening. Failure to perform a crossmatch prior to transplant **is not** a deficiency provided emergency transplant circumstances are documented.

For solid organ transplants (renal, heart, liver, lung, small intestine):

1. Determine what tests are performed for potential kidney and pancreas recipients.

2. Determine what tests are performed on living-related or unrelated donors and cadaver donors referred to the laboratory.

3. Determine if the laboratory performs HLA typing using complement dependent lymphocytotoxicity testing (antigen level) and/or DNA testing (allele level);

4. Compare policies for pre-sensitized patients with laboratory antibody screening and identification protocols for consistency;

5. Verify that the laboratory is using a crossmatch technique with increased sensitivity; and

6. Deviations from the established protocols should be documented by the laboratory, indicating the reason for the deviation, e.g., transplant physician request, emergency transplant.

For transfusions (platelet support of refractory patients):

1. Determine what tests are performed on recipients and donors. Recipients are usually HLA-A and HLA-B typed, e.g., platelets do not have Class II (HLA-DR, DQ) antigens on their surface. Donors may be typed by the laboratory, a blood center or a donor program laboratory. HLA typing may be performed using complement dependent lymphocytotoxicity testing (antigen level) and/or DNA testing (allele level).

2. Determine if the laboratory performs antibody screening/identification on the recipient. Compare with the laboratory protocol for antibody screening and identification.

3. Determine if the laboratory performs Class I crossmatch testing.

For tissue transplant (bone marrow/stem cells, etc.)

1. Determine what level of HLA typing is performed on recipients and donors. For bone marrow/stem cell transplantation, recipients are at a minimum HLA-A and HLA-B typed by complement dependent lymphocytotoxicity and/or DNA testing. Recipients should be HLA-DR typed by high resolution DNA typing (allele level). Donors may be typed by the laboratory or a donor program laboratory.

2. Determine if the laboratory performs crossmatch testing, when a selected potential donor has an HLA mismatch. Determine if the laboratory performs Class II compatibility to evaluate Class II identity by either MLC testing, high resolution DNA typing, or a family study.

Probes §493.1278(f)

What is the laboratory's policy/protocol on referring patient specimens for testing at another laboratory?

What is the laboratory's policy/protocol on accepting HLA typing results obtained at another laboratory (i.e., does the laboratory reconfirm (repeat) testing)?