§493.1278 Standard: Histocompatibility

(d) Antibody Screening. The laboratory must do the following:

(d)(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.

(d)(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.

(d)(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

***Interpretive* Guidelines §493.1278(d)(1)-(d)(3)**

An antibody screen is performed to identify whether a patient's serum contains antibodies to one or more HLA antigens. This is accomplished by screening the serum against target antigens from a suitable panel appropriate for the population served, i.e., a variety of ethnic groups. Results are expressed as percent reactive antibodies (PRA).

The panel of antigens used must include all of the HLA antigens to which the most common HLA antibodies are formed. Cell panels of known HLA type must be available to prove the specificity of new antibodies. The serum cell panel should be consistent from month to month and from lot to lot. Verify that the frequency of each antigen represented does not vary significantly.

An example of PRA differences from panel to panel:

If a patient demonstrates a HLA-A2 antibody and the cell panel contains 15 A2 positive cells out of 100, the patient's PRA on this tray will be 15%. If the same patient is tested against a panel where there are 37 A2 positive cells out of 100, the patient's PRA will increase to 37%. The number of A2 positive cells on this laboratory's cell panel should reflect the frequency observed in the population it serves; e.g., 15-20% of the local population possess the HLA-A2 antigen.

If the laboratory tests for antibodies to Class II antigens, the laboratory should have a procedure for removing Class I antibodies or should use purified Class II antigens. Class II antigens (HLA-DR, DQ) are found only on the B cell subset of lymphocytes. B cells also have a high density of Class I antigens (HLA-A, B, C), which are found on all nucleated cells. If a patient has a significant titer of Class I antibodies, it may result in a false positive Class II antibody test result. Platelet absorption is one method of removing the Class I antibodies.

Verify that the laboratory's antibody screening technique is as sensitive as the crossmatch method it uses to ensure optimum compatibility.