

§493.1278 Standard: Histocompatibility

(e)(2) Have available and follow written criteria for the following:

(e)(2)(i) Selecting appropriate patient serum samples for crossmatching.

***Interpretive* Guidelines §493.1278(e)(2)(i)**

The laboratory must have clearly defined protocols for selection of serum for crossmatch testing. There are numerous acceptable protocols for the selection of crossmatch samples which vary from transplant center to center. However, every effort should be made to procure a specimen at the time of transplant or unless the laboratory can clearly establish that the patient did not receive a blood transfusion or other alloimmunizing event between the times of specimen collection and transplant date.

Review patient transplant records for lymphocyte crossmatch results. Verify serum selected for crossmatching against antibody screening/identification records. Verify if the serum is tested at an optimal dilution. Crossmatches are performed with donor T cells

(T lymphocytes) or unseparated lymphocytes. Crossmatches with donor B cells (B lymphocytes) may be performed.

Probes §493.1278(e)(2)(i)

Does the laboratory's policies and procedures specify which patient serum samples are to be used for crossmatching (e.g., renal, pancreas, heart, lung, small intestine or liver transplants)?

(e)(2)(ii) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

***Interpretive* Guidelines §493.1278(e)(2)(ii)**

There are various techniques for the isolation of donor cells for use in crossmatching e.g., immunomagnetic beads, monoclonal antibody preparations, density gradient (ficoll hypaque). Crossmatching techniques utilizing cellular extracts (solubilized antigens and nucleic acid) are not well documented in the clinical setting.

Determine if the laboratory follows manufacturer's product insert procedures. Use D5479.

Verify that the laboratory has established procedures and criteria for cell preparation viability, purity and quantity (i.e. peripheral blood, lymph node, spleen).