

**§ 493.1261**

with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section.

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

**§ 493.1261 Condition: Oral pathology.**

To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and § 493.1259 of this subpart. All quality control activities must be documented.

**§ 493.1263 Condition: Radiobioassay.**

To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

**§ 493.1265 Condition:  
Histocompatibility.**

In addition to meeting the applicable requirements for general quality control in §§ 493.1201 through 493.1221, for quality control for general immunology in § 493.1241 of this subpart and for immunohematology in § 493.1269 of this subpart, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) For renal allotransplantation, the laboratory must meet the following requirements:

(1) The laboratory must have available and follow criteria for—

(i) Selecting appropriate patient serum samples for crossmatching;

(ii) The technique used in crossmatching;

(iii) Preparation of donor lymphocytes for crossmatching; and

(iv) Reporting crossmatch results;

(2) The laboratory must—

(i) Have available results of final crossmatches before an organ or tissue is transplanted; and

(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing,

for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

(3) The laboratory's storage and maintenance of both recipient sera and reagents must—

(i) Be at an acceptable temperature range for sera and components;

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and

(iii) Ensure that all specimens are properly identified and easily retrievable;

(4) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;

(5) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;

(6) The laboratory must—

(i) HLA type all potential transplant recipients;

(ii) Type cells from organ donors referred to the laboratory; and

(iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;

(7) The laboratory must have available and follow criteria for—

(i) The preparation of lymphocytes for HLA-A, B and DR typing;

(ii) Selecting typing reagents, whether locally or commercially prepared;

(iii) The assignment of HLA antigens; and

(iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A,B and DR specificities for which reagents are readily available;

(8) The laboratory must—

(i) Screen potential transplant recipient sera for preformed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected;

(A) At the time of the recipient's initial HLA typing; and

(B) Thereafter, following sensitizing events and upon request; and

(ii) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits—