

§ 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,

42 CFR Ch. IV (10-1-00 Edition)

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—

(A) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and

(B) If the laboratory uses frozen panels, it must have a suitable storage system;

(9) The laboratory must check—

(i) Each typing tray using—

(A) Positive control sera;

(B) Negative control sera; and

(C) Positive controls for specific cell types when applicable (i.e., T cells, B cells, and monocytes); and

(ii) Each compatibility test (i.e. mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level;

(10) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

(11) If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with § 493.1269 of this subpart;

(12) If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures;

(13) At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained; and

(14) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate inter-laboratory reproducibility.

(b) If the laboratory performs histocompatibility testing for—

(1) Transfusions and other non-renal transplantation, excluding bone marrow and living transplants, all the re-

quirements specified in this section, as applicable, except for the performance of mixed lymphocyte cultures, must be met;

(2) Bone marrow transplantation, all the requirements specified in this section, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met; and

(3) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.

(c) Laboratories performing HLA typing for disease-associated studies must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.

(d) For laboratories performing organ donor HIV testing the requirements of § 493.1241 of this subpart for the transfusion of blood and blood products must be met.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§ 493.1267 Condition: Clinical cytogenetics.

To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells