

§ 493.1267

42 CFR Ch. IV (10-1-99 Edition)

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 requirements 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 karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.

**§ 493.1269 Condition:
Immunoematology.**

To meet the quality control requirements for immunoematology, the laboratory must comply with the applicable requirements in §§ 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) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions, if provided, and as applicable, with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR part 640 *et seq.*

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B

grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.

§ 493.1271 Condition: Transfusion services and bloodbanking.

If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunoematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in §§ 493.1273 through 493.1285.

[58 FR 5233, Jan. 19, 1993]

**§ 493.1273 Standard;
Immunoematological collection,
processing, dating periods, labeling
and distribution of blood and blood
products.**

In addition to the requirements in paragraphs (a) through (d) of this section, the facility must also meet the applicable quality control requirements in §§ 493.1201 through 493.1221 of this part.

(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606, and the testing laboratory must meet the applicable requirements of part 493.

(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.