

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	5	5
B	5	10	5	5
C	5	0	10	10
D	0	-5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (-10) points for an incorrect response on a 20-slide test set.

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	0	0
B	2.5	5	0	0
C	2.5	0	5	2.5
D	0	-10	2.5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	2.5	2.5
B	2.5	5	2.5	2.5
C	2.5	0	5	5
D	0	-10	5	5

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.959 Immunohematology.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—

- (1) Those that perform ABO group and/or D (Rho) typing;
- (2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;
- (3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and

(4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

- ABO group (excluding subgroups)
- D (Rho) typing
- Unexpected antibody detection
- Compatibility testing
- Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

§ 493.1101

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(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte} \times 100}{\text{Analyte score for the testing event}}$$

Total number of challenges for the analyte

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges} \times 100}{\text{Testing event score}}$$

Total number of all challenges

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7162, Feb. 28, 1992, unless otherwise noted.

§ 493.1101 Condition: Patient test management; moderate complexity (including the subcategory), or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transpor-

tion, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards as they apply to the testing performed.

[60 FR 20048, Apr. 24, 1995]

§ 493.1103 Standard; Procedures for specimen submission and handling.

(a) The laboratory must have available and follow written policies and procedures for each of the following, if applicable: Methods used for the preparation of patients; specimen collection; specimen labeling; specimen preservation; conditions for specimen transportation; and specimen processing. Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported.

(b) If the laboratory accepts referral specimens, written instructions must be available to clients and must include, as appropriate, the information specified in paragraph (a) of this section.

(c) Oral explanation of instructions to patients for specimen collection, including patient preparation, may be used as a supplement to written instructions where applicable.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.1105 Standard; Test requisition.

The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization. Records of test requisitions or test authorizations must be retained for a minimum of two years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two years and