

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.

(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:

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

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

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

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, transportation, 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]