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

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

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

EFFECTIVE DATE NOTE: At 87 FR 41242, July 11, 2022, § 493.959 was amended by revising paragraphs (b) and (d)(1) and (2), effective July 11, 2024. For the convenience of the user, the revised text is set forth as follows:

§ 493.959 Immunohematology.

* * * * *

(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.

(d) * * *

(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 10 or more referee laboratories or 95 percent or more of all participating laboratories except for antibody identification. To determine the accuracy of a laboratory's response for antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent or more of 10 or more referee laboratories or 95 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

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

TABLE 2 TO PARAGRAPH (d)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

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

* * * * *

Subpart J—Facility Administration for Nonwaived Testing

SOURCE: 68 FR 3703, Jan. 24, 2003, unless otherwise noted.

§ 493.1100 Condition: Facility administration.

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§ 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

(a) *Reporting of SARS–CoV–2 test results.* During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19 (hereinafter referred to as a ''SARS–CoV–2 test'') must report SARS–CoV–2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

(b) [Reserved]

[68 FR 3703, Jan. 24, 2003, as amended at 85 FR 54873, Sept. 2, 2020]