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analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

*Criteria for Acceptable Performance*

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification .....	90% or greater consensus on identification.

Analyte or test	Criteria for acceptable performance
White blood cell differential ...	Target ±3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count .....	Target ±6%.
Hematocrit (Excluding spun hematocrits) .....	Target ±6%.
Hemoglobin .....	Target ±7%.
Leukocyte count .....	Target ±15%.
Platelet count .....	Target ±25%.
Fibrinogen .....	Target ±20%.
Partial thromboplastin time ...	Target ±15%.
Prothrombin time .....	Target ±15%.

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

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

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

(5) To determine the overall testing event score, the number of correct re-

sponses for all analytes must be averaged using the following formula:

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

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

**§ 493.945 Cytology; gynecologic examinations.**

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in §§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2). If slide preparations are still subject to retention by the laboratory, they may

be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after

notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in § 493.855.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or re-evaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under § 493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3) (i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under

§§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	Description
A .....	Unsatisfactory for diagnosis due to: (1) Scant cellularity. (2) Air drying. (3) Obscuring material (blood, inflammatory cells, or lubricant).
B .....	Normal or Benign Changes—includes: (1) Normal, negative or within normal limits. (2) Infection other than Human Papillomavirus (HPV) (e.g., <i>Trichomonas vaginalis</i> , changes or morphology consistent with <i>Candida</i> spp., <i>Actinomyces</i> spp. or <i>Herpes simplex</i> virus). (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C .....	Low Grade Squamous Intraepithelial Lesion—includes: (1) Cellular changes associated with HPV. (2) Mild dysplasia/CIN-1.
D .....	High Grade Lesion and Carcinoma—includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (-5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is "high grade squamous intraepithelial lesion" (category "D" on the scoring system chart) and an examinee calls it

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“normal or negative” (category “B” on the scoring system chart), then the examinee’s point value on that slide is calculated as minus five (–5). Each slide is scored individually in the same manner. The individual’s score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide test set. (See table at (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 .....	10	0	0	0
B .....	5	10	0	0
C .....	5	0	10	5
D .....	0	–5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (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 .....	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; 68 FR 3702, Jan. 24, 2003]

§ 493.959 **Immunoematology.**

(a) *Types of services offered by laboratories.* In immunoematology, 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 anti-body identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunoematology, 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