TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE—Continued

| The criteria for acceptable performance are—Analyte or test | Criteria for acceptable performance |
|---|---|
| Lithium | Target Value ±15% or ±0.3 mmol/L (greater). |
| Phenobarbital | Target Value ±15% or ±2 mcg/mL (greater). |
| Phenytoin total | Target Value ±15% or ± 2 mcg/mL (greater). |
| Salicylate | Target Value ±15% or ±2 mcg/mL (greater). |
| Theophylline | Target Value ±20%. |
| Tobramycin | Target Value ±20%. |
| Valproic Acid, total | Target Value ±20%. |
| Vancomycin | Target Value ±15% or ±2 mcg/mL (greater). |

* * * * *

### § 493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, 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 values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *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*

Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

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

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each 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. |
| 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%. |

| Analyte or test | Criteria for acceptable performance |
|---|---|
| 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 responses for all analytes must be averaged using the following formula:

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

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

EFFECTIVE DATE NOTE: At 87 FR 41241, July 11, 2022, § 493.941 was amended by revising paragraphs (a), (b), and (c)(1) and (2), effective July 11, 2024. For the convenience of the user, the added and revised text is set forth as follows:

**§ 493.941 Hematology (including routine hematology and coagulation).**

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, 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 values that would be expected in patient specimens. The samples may be provided through mailed shipments.

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

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST PROCEDURE

| |
|---|
| Cell identification. |
| White blood cell differential. |
| Erythrocyte count. |
| Hematocrit (excluding spun microhematocrit). |
| Hemoglobin. |
| Leukocyte count. |
| Platelet count. |
| Fibrinogen. |
| Partial thromboplastin time. |
| Prothrombin time (seconds or INR). |

(c) * * *

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each 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 (SD) the response differs from the target value.

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

| The criteria for acceptable performance are: Analyte or test | Criteria for acceptable performance |
|---|---|
| Cell identification | 80% or greater consensus on identification. |

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE—Continued

| The criteria for acceptable performance are: 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 ±4%. |
| Hematocrit (Excluding spun hematocrit). | Target ±4%. |
| Hemoglobin ..... | Target ±4%. |
| Leukocyte count ..... | Target ±10%. |
| Platelet count ..... | Target ±25%. |
| Fibrinogen ..... | Target ±20%. |
| Partial thromboplastin time .... | Target ±15%. |
| If a laboratory reports a prothrombin time in both INR and seconds, the INR should be reported to the PT provider program. | |
| Prothrombin time (seconds or INR). | Target ±15%. |

* * * * *

### § 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 reevaluation 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