Analyte or Test

Cortisol
Free Thyroxine
Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(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 response for qualitative and quantitative endocrinology tests or analytes, a 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 endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology 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 must be determined by 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
Cortisol	Target value ±25%.
Free Thyroxine	Target value ±3 SD.
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	Target value ±3 SD positive or negative.
T3 Uptake	Target value ±3 SD.
Triiodothyronine	Target value ±3 SD.
Thyroid-stimulating hormone	Target value ±3 SD.
Thyroxine	Target value ±20% or 1.0 mcg/dL (greater).

(3) The criterion for acceptable performance for qualitative endocrinology 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:

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

(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]

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual 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 clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS 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 serum, plasma, or blood samples.

Analyte or Test Procedure

Alcohol (blood)	Phenytoin
Blood lead	Primidone
Carbamazepine	Procainamide (and metabolite)
Digoxin	Quinidine
Ethosuximide	Theophylline
Gentamicin	Tobramycin
Lithium	Valproic Acid
Phenobarbital	

(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 (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology 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 toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology 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 must be determined by using fixed criteria based on the percentage difference from the target value

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood	Target Value ±25%.
Blood lead	Target Value ±10% or 4 mcg/dL (greater).
Carbamazepine	Target Value ±25%.
Digoxin	Target Value ±20% or ±0.2 ng/mL (greater).
Ethosuximide	Target Value ±20%.
Gentamicin	Target Value ±25%.
Lithium	Target Value ±0.3 mmol/L or ±20% (greater).
Phenobarbital	Target Value ±20%
Phenytoin	Target Value ±25%.
Primidone	Target Value ±25%.
Procainamide (and metabolite).	Target Value ±25%.
Quinidine	Target Value ±25%.
Tobramycin	Target Value ±25%.
Theophylline	Target Value ±25%.
Valproic Acid	Target Value ±25%.

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

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

(4) 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]

§ 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%.
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: