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. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative immunology analytes or tests, 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 or the number of standard deviations (SDs) 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
Alpha-1 antitrypsin	Target value ± 20%.
Alpha-fetoprotein (tumor marker).	Target value ± 20%.
Antinuclear antibody (ANA)	Target value ±2 dilutions or positive or negative.
Antistreptolysin O	Target value ±2 dilutions or positive or negative.
Anti-Human Immunodeficiency virus (HIV).	Reactive (positive) or nonreactive (negative).
Complement C3	Target value ±15%.
Complement C4	Target value ±20% or ±5 mg/dL (greater).
C-reactive protein (HS)	Target value ±30% or ±1 mg/L (greater).
HBsAg	Reactive (positive) or nonreactive (negative).
Anti-HBc	Reactive (positive) or nonreactive (negative).
HBeAg	Reactive (positive) or nonreactive (negative).
Anti-HBs	Reactive (positive) or nonreactive (negative).
Anti-HCV	Reactive (positive) or nonreactive (negative).
IgA	Target value ±20%.
IgE	Target value ±20%.
IgG	Target value ±20%.
IgM	Target value ±20%.
Infectious mononucleosis	Target value ±2 dilutions or positive or negative.
Rheumatoid factor	Target value ±2 dilutions or positive or negative.
Rubella	Target value ±2 dilutions or positive or negative or immune or nonimmune.

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§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, 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 clinically relevant range of values that would be expected in patient specimens. The specimens 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 listed below is five serum, plasma or blood samples.

Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(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 chemistry 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 routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry 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
Alanine aminotransferase (ALT/SGPT).	Target value ±20%.
Albumin	Target value ±10%.
Alkaline phosphatase	Target value ±30%.
Amylase	Target value ±30%.
Aspartate aminotransferase (AST/SGOT).	Target value ±20%.
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater).
Blood gas pO2	Target value ±3 SD.
pCO2	Target value ±5 mm Hg or ±8% (greater).
pH	Target value ±0.04.
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein.	Target value ±30%.
Creatine kinase	Target value ±30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ±3SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use.	Target value ±6 mg/dl or ±10% (greater).
Iron, total	Target value ±20%.
Lactate dehydrogenase (LDH).	Target value ±20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ±30%.
Magnesium	Target value ±25%.
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L.
Total Protein	Target value ±10%.
Triglycerides	Target value ±25%.
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%.

(3) The criterion for acceptable performance for qualitative routine chemistry 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 68 FR 3702, Jan. 24, 2003]

EFFECTIVE DATE NOTE: At 87 FR 41238, July 11, 2022, § 493.931 was amended by revising

paragraphs (a), (b), and (c)(1) and (2), effective July 11, 2024. For the convenience of the user, the revised text is set forth as follows:

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, 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 clinically relevant range of values that would be expected in patient specimens. The specimens 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 listed below is five serum, plasma or blood samples.

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

Alanine aminotransferase (ALT/SGPT).
Albumin.
Alkaline phosphatase.
Amylase.
Aspartate aminotransferase (AST/SGOT).
Bilirubin, total.
Blood gas (pH, pO2, and pCO2).
B-natriuretic peptide (BNP).
proBNP.
Calcium, total.
Carbon dioxide.
Chloride.
Cholesterol, total.
Cholesterol, high density lipoprotein.
Cholesterol, low density lipoprotein, (direct measurement).
Creatine kinase (CK).
CK–MB isoenzymes.
Creatinine.
Ferritin.
Gamma glutamyl transferase.
Glucose (Excluding measurements on devices cleared by FDA for home use).
Hemoglobin A1c.
Iron, total.
Lactate dehydrogenase (LDH).
Magnesium.
Phosphorus.
Potassium.
Prostate specific antigen (PSA), total.
Sodium.
Total iron binding capacity (TIBC) (direct measurement).
Total Protein.
Triglycerides.
Troponin I.
Troponin T.
Urea Nitrogen.
Uric Acid.

(c) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry 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 chemistry 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 (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
Alanine aminotransferase (ALT/SGPT).	Target value ±15% or ±6 U/L (greater).
Albumin	Target value ±8%.
Alkaline phosphatase	Target value ±20%.
Amylase	Target value ±20%.
Aspartate aminotransferase (AST/SGOT).	Target value ±15% or ±6 U/L (greater).
Bilirubin, total	Target value ±20% or ±0.4 mg/dL (greater).
Blood gas pCO2	Target value ±8% or ±5 mm Hg (greater).
Blood gas pO2	Target value ±15% or ±15 mmHg (greater).
Blood gas pH	Target value ±0.04.
B-natriuretic peptide (BNP)	Target value ±30%.
Pro B-natriuretic peptide (proBNP).	Target value ±30%.
Calcium, total	Target value ±1.0 mg/dL.
Carbon dioxide	Target value ±20%.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein (HDL).	Target value ±20% or ±6 mg/dL (greater).
Cholesterol, low density lipoprotein (LDL), direct measurement.	Target value ±20%.
Creatine kinase (CK)	Target value ±20%.
CK–MB isoenzymes	Target value ± 25% or ±3 ng/mL (greater) or MB elevated (presence or absence).
Creatinine	Target value ±10% or ±0.2 mg/dL (greater).
Ferritin	Target value ±20%.

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

The criteria for acceptable performance are— Analyte or test	Criteria for acceptable performance
Gamma glutamyl transferase	Target value ±15% or ±5 U/L (greater).
Glucose (excluding measurements devices cleared by FDA for home use.).	Target value ±8% or ±6 mg/dL (greater).
Hemoglobin A1c	Target value ±8%.
Iron, total	Target value ±15%.
Lactate dehydrogenase (LDH).	Target value ±15%.
Magnesium	Target value ±15%.
Phosphorus	Target value ± 10% or ±0.3 mg/dL (greater).
Potassium	Target value ±0.3 mmol/L.
Prostate Specific Antigen, total.	Target value ±20% or ±0.2 ng/mL (greater).
Sodium	Target value ±4 mmol/L.
Total Iron Binding Capacity (TIBC). (direct measurement).	Target value ±20%.
Total Protein	Target value ±8%.
Triglycerides	Target value ±15%.
Troponin I	Target value ± 30% or ±0.9 ng/mL (greater).
Troponin T	Target value ±30% or ±0.2 ng/mL (greater).
Urea nitrogen	Target value ±9% or ±2 mg/dL (greater).
Uric acid	Target value ±10%.

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§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, 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 clinically relevant 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 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, blood, or urine samples.

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