

Analyte or test	Criteria for acceptable performance
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%.

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 90 percent of ten or more referee laboratories or 90 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.

(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:

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

**§ 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

*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]

**§ 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
Digoxin	(and metabolite)
Ethosuximide	Quinidine
Gentamicin	Theophylline
Lithium	Tobramycin
Phenobarbital	Valproic 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 (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 90 percent of ten or more referee laboratories or 90 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).