§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).

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Analyte or test	Criteria for acceptable per-formance
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%.

Analyte or test	Criteria for acceptable per-formance
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:

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

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

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

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