§ 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