

## Centers for Medicare &amp; Medicaid Services, HHS

§ 493.931

Analyte or test	Criteria for acceptable performance	Analyte or test	Criteria for acceptable performance
Antinuclear antibody .....	Target value $\pm 2$ dilutions or positive or negative.	Rheumatoid factor .....	Target value $\pm 2$ dilutions or positive or negative.
Antistreptolysin O .....	Target value $\pm 2$ dilution or positive or negative.	Rubella .....	Target value $\pm 2$ dilutions or immune or nonimmune or positive or negative.
Anti-Human Immuno-deficiency virus.	Reactive or nonreactive.		
Complement C3 .....	Target value $\pm 3$ SD.		
Complement C4 .....	Target value $\pm 3$ SD.		
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or non-reactive (negative).		
IgA .....	Target value $\pm 3$ SD.		
IgE .....	Target value $\pm 3$ SD.		
IgG .....	Target value $\pm 25\%$ .		
IgM .....	Target value $\pm 3$ SD.		
Infectious mononucleosis .....	Target value $\pm 2$ dilutions or positive or negative.		

(3) The criterion for acceptable performance for qualitative general immunology 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]

#### § 493.929 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 ship-

ments 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, pO<sub>2</sub>, and pCO<sub>2</sub>)  
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