

Centers for Medicare & Medicaid Services, HHS

§ 493.931

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.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein (tumor marker)	Target value ±3 SD.
Antinuclear antibody	Target value ±2 dilutions or positive or negative.
Antistreptolysin O	Target value ±2 dilution or positive or negative.
Anti-Human Immunodeficiency virus	Reactive or nonreactive.
Complement C3	Target value ±3 SD.

Analyte or test	Criteria for acceptable performance
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg)	Reactive (positive) or non-reactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value ±25%.
IgM	Target value ±3 SD.
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 immune or nonimmune 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 re-

sponses 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 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