

§ 493.921

must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be $1/(1+1) \times 100 = 50$ percent.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§ 493.923 and 493.927.

§ 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, 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.

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The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response 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 proficiency testing program must indicate the minimum concentration, by method, that will be considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method 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. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ± 1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses 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]

§ 493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, 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 full range of reactivity from highly reactive to nonreactive. 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 the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure

Alpha-1 antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

(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 quantitative and qualitative immunology 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 proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, 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 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.
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 $\pm 25\%$.
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: