

formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(3) The content of an approved program must vary over time, as appropriate. The types of parasites included annually must be representative of the following major groups of medically important parasites, if appropriate for the sample sources:

- (i) Intestinal parasites; and
- (ii) Blood and tissue parasites.

(4) The program must provide at least five samples per testing event that include challenges that contain parasites and challenges that are devoid of parasites.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the reportable parasites to be detected by direct parasite antigen detection, detection of the presence or absence of parasites without identification, and identification of parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare each response with the response which reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify or concentrate and identify the parasites to the highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

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

(5) The performance criterion for the detection and identification of parasites includes one of the following:

(i) The performance criterion for the detection of the presence or absence of parasites without identification is the correct detection of the presence or absence of parasites without identification. The score is the number of correct responses divided by the num-

ber of samples to be tested, multiplied by 100.

(ii) The performance criterion for the identification of parasites is the total number of correct responses for parasite identification submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported and not found in rare numbers by the program's referencing process. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be  $1/(1+1) \times 100 = 50$  percent.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) through (5) of this section.

#### § 493.919 Virology.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, 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 samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must furnish HHS with a description of samples

that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample 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.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system 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]

EFFECTIVE DATE NOTE: At 87 FR 41236, July 11, 2022, §493.919 was revised, effective July 11, 2024. For the convenience of the user, the revised text is set forth as follows:

#### §493.919 Virology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for virology, 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 samples may be provided to the laboratory through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

- (i) Viral antigen detection; and
- (ii) Detection and identification of viruses.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. The program must include other important emerging viruses and viruses commonly occurring in patient specimens.

(3) The content of an approved program must vary over time, as appropriate. If appropriate for the sample sources, the types of viruses included annually must be representative of the following major groups of medically important viruses:

- (i) Respiratory viruses;
- (ii) Herpes viruses;
- (iii) Enterovirus; and
- (iv) Intestinal viruses.

(b) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the viruses to be reported by direct viral antigen detection, and detection and identification of viruses. To determine the accuracy of a laboratory's response, the program must compare each response with the response which reflects

agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the viruses to the highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

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

(5) The performance criterion for the detection and identification of viruses is the total number of correct responses for viral detection and identification submitted by the laboratory divided by the number of viruses present plus the number of incorrect virus reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be  $1/(1+1) \times 100 = 50$  percent.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) and (5) of this section.

**§ 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. 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  $\pm 1$  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:

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