an additional organism, which was not present, the sample grade would be 1/(1+1)x100=50 percent.

(4) 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) or (c)(4), or both, of this section.

§493.917 Parasitology

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

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) Program content and frequency of challenges. To be approved for proficiency testing in parasitology, 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’s option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year 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. Samples must include both formalized 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.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

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

(1) The program must determine the reportable 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 scoring a laboratory’s performance; such findings are neutral.

To determine the accuracy of a laboratory’s response, 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.

(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 determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same
§ 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 included 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 (c)(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

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