

mycobacteria to be reported by detection of the presence or absence of mycobacteria without identification, and identification of mycobacteria. To determine the accuracy of each of the laboratory's responses, the program must compare each response with the response that 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 organisms 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 paragraph (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

(4) The performance criterion for acid-fast stains is positive or negative or the presence or absence of acid-fast organisms. 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 mycobacteria includes one of the following:

(i) The performance criterion for the detection of the presence or absence of mycobacteria without identification is the correct detection of the presence or absence of mycobacteria without identification. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of mycobacteria is the total number of correct responses for mycobacterial identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms 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 mycobacteria in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms 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 in mycobacteriology is the average of the scores determined under paragraphs (b)(4) through (5) of this section based on the type of service offered by the laboratory.

§493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;

(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;

(3) Those that isolate and perform identification of all organisms to the genus level; and

(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, 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 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 contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(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. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

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

Candida albicans

§ 493.917

Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Microsporium sp.
Acremonium sp.
Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
*Blastomyces dermatitidis*¹
Zygomycetes sp.

¹ NOTE: Provided as a nonviable sample.

(c) *Evaluation of a 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 organisms. 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 organisms to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. 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 present, the sample grade would be $\frac{1}{1+1} \times 100 = 50$ percent.

(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be

42 CFR Ch. IV (10–1–23 Edition)

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.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 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 challenge.* 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 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.