

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

### Subpart I—Proficiency Testing Programs for Nonwaived Testing

SOURCE: 57 FR 7151, Feb. 28, 1992, unless otherwise noted.

#### § 493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private non-profit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

(b) Demonstrate to HHS that it has—

(1) The technical ability required to—

(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and with the frequency specified in §§ 493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual's performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;

(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

(7) A process to resolve technical, administrative, and scientific problems about program operations;

(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and

(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

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