

testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with § 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003; 79 FR 27157, May 12, 2014]

EFFECTIVE DATE NOTE: At 87 FR 41232, July 11, 2022, § 493.801 was amended by redesignating paragraphs (b)(3) through (6) as paragraphs (b)(4) through (7), respectively; and adding new paragraph (b)(3), effective July 11, 2024. For the convenience of the user, the added text is set forth as follows:

§ 493.801 Condition: Enrollment and testing of samples.

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(b) * * *

(3) The laboratory must report PT results for microbiology organism identification to the highest level that it reports results on patient specimens.

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§ 493.803 Condition: Successful participation.

(a) Each laboratory performing non-waived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

[57 FR 7146, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995; 63 FR 26737, May 14, 1998; 68 FR 3702, Jan. 24, 2003]

§ 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory