

Centers for Medicare & Medicaid Services, HHS

§ 493.5

evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993; 60 FR 20043, Apr. 24, 1995; 63 FR 26732, May 14, 1998; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003; 79 FR 25480, May 2, 2014; 79 FR 27157, May 12, 2014; 85 FR 54873, Sept. 2, 2020]

EFFECTIVE DATE NOTE: At 87 FR 41232, July 11, 2022, § 493.2 was amended by adding the definitions of “Acceptance limit” and “Peer group” in alphabetical order; and revising the definition of “Target value”, effective July 11, 2024. For the convenience of the user, the added and revised text is set forth as follows:

§ 493.2 Definitions.

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Acceptance limit means the symmetrical tolerance (plus and minus) around the target value.

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Peer group means a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number level.

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Target value for quantitative tests means:

(1) If the peer group consists of 10 participants or greater:

(i) The mean of all participant responses after removal of outliers (that is, those responses greater than three standard deviations from the original mean, as applicable);

(ii) The mean established by a definitive method or reference methods; or

(iii) If a definitive method or reference methods are not available, the mean of a peer group; or

(2) If the peer group consists of fewer than 10 participants, the mean of all participant responses after removal of outliers (as defined in paragraph (1) of this definition) unless acceptable scientific reasons are avail-

able to indicate that such an evaluation is not appropriate.

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§ 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 60 FR 20043, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.