

§ 493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

- (1) Are cleared by FDA for home use;
- (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

- (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:
 - (i) Bilirubin;
 - (ii) Glucose;
 - (iii) Hemoglobin;
 - (iv) Ketone;
 - (v) Leukocytes;
 - (vi) Nitrite;
 - (vii) pH;
 - (viii) Protein;
 - (ix) Specific gravity; and
 - (x) Urobilinogen.
- (2) Fecal occult blood;
- (3) Ovulation tests—visual color comparison tests for human luteinizing hormone;
- (4) Urine pregnancy tests—visual color comparison tests;
- (5) Erythrocyte sedimentation rate—non-automated;
- (6) Hemoglobin—copper sulfate—non-automated;
- (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;
- (8) Spun microhematocrit; and
- (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

- (1) Follow manufacturers' instructions for performing the test; and
- (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

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§ 493.17 Test categorization.

(a) *Categorization by criteria.* Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

(1) *Knowledge.* (i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) *Score 3.* Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) *Training and experience.* (i) *Score 1.* (A) Minimal training is required for