

## Food and Drug Administration, HHS

## § 660.2

(b) FDA will publish a list of approved alternative procedures and exceptions periodically in the FEDERAL REGISTER.

[55 FR 10423, Mar. 21, 1990, as amended at 62 FR 39903, July 24, 1997]

### PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

#### Subpart A—Antibody to Hepatitis B Surface Antigen

Sec.

- 660.1 Antibody to Hepatitis B Surface Antigen.
- 660.2 General requirements.
- 660.3 Reference panel.
- 660.4 Potency test.
- 660.5 Specificity.
- 660.6 Samples; protocols; official release.

#### Subpart B [Reserved]

#### Subpart C—Blood Grouping Reagent

- 660.20 Blood Grouping Reagent.
- 660.21 Processing.
- 660.22 Potency requirements with reference preparations.
- 660.25 Potency tests without reference preparations.
- 660.26 Specificity tests and avidity tests.
- 660.28 Labeling.

#### Subpart D—Reagent Red Blood Cells

- 660.30 Reagent Red Blood Cells.
- 660.31 Suitability of the donor.
- 660.32 Collection of source material.
- 660.33 Testing of source material.
- 660.34 Processing.
- 660.35 Labeling.
- 660.36 Samples and protocols.

#### Subpart E—Hepatitis B Surface Antigen

- 660.40 Hepatitis B Surface Antigen.
- 660.41 Processing.
- 660.43 Potency test.
- 660.44 Specificity.
- 660.45 Labeling.
- 660.46 Samples; protocols; official release.

#### Subpart F—Anti-Human Globulin

- 660.50 Anti-Human Globulin.
- 660.51 Processing.
- 660.52 Reference preparations.
- 660.53 Controls for serological procedures.
- 660.54 Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

660.55 Labeling.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263, 263a, 264.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

#### Subpart A—Antibody to Hepatitis B Surface Antigen

##### § 660.1 Antibody to Hepatitis B Surface Antigen.

(a) *Proper name and definition.* The proper name of this product shall be Antibody to Hepatitis B Surface Antigen. The product is defined as a preparation of serum containing antibody to hepatitis B surface antigen.

(b) *Source.* The source of this product shall be plasma or blood, obtained aseptically from animals immunized with hepatitis B surface antigen, which have met the applicable requirements of § 600.11 of this chapter, or from human donor whose blood is positive for hepatitis B surface antigen.

[40 FR 29711, July 15, 1975]

##### § 660.2 General requirements.

(a) *Processing.* The processing method shall be one that has been shown to consistently yield a specific and potent final product free of properties which would adversely affect the test results when the product is tested by the methods recommended by the manufacturer in the package enclosure.

(b) *Ancillary reagents and materials.* All ancillary reagents and materials supplied in the package with the product shall meet generally accepted standards of purity and quality and shall be effectively segregated and otherwise manufactured in a manner (such as heating at 60 °C. for 10 hours) that will reduce the risk of contaminating the product and other biological products. Ancillary reagents and materials accompanying the product which are used in the performance of the test as described by the manufacturer's recommended test procedures shall have been shown not to adversely affect the

### § 660.3

product within the prescribed dating period.

(c) *Labeling.* In addition to the items required by other applicable labeling provisions of this subchapter, the following shall also be included:

(1) Indication of the source of the product immediately following the proper name on both the final container and package label, e.g., human, guinea pig.

(2) Name of the test method(s) recommended for the product on the package label and on the final container label when capable of bearing a full label (see § 610.60(a) of this chapter).

(3) A warning on the package label and on the final container label if capable of bearing a full label (see § 610.60(a) of this chapter) indicating that the product and antigen if supplied, shall be handled as if capable of transmitting hepatitis.

(4) If the product is dried, the final container label shall indicate "Reconstitution date: \_\_\_\_\_" and a statement indicating the period within which the product may be used after reconstitution.

(5) The package shall include a package enclosure providing (i) adequate instructions for use, (ii) a description of all recommended test methods, and (iii) warnings as to possible hazards, including hepatitis, in handling the product and any ancillary reagents and materials accompanying the product.

(d) *Final container.* A final container shall be sufficiently transparent to permit visual inspection of the contents for presence of particulate matter and increased turbidity. The effectiveness of the contents of a final container shall be maintained throughout its dating period.

(e) *Date of manufacture.* The date of manufacture of Antibody to Hepatitis B surface Antigen that has been iodinated with radioactive iodine ( $^{125}\text{I}$ ) shall be the day of labeling the antibody with the radionuclide.

(f) *Retention samples.* Each manufacturer shall retain representative samples of the product in accordance with § 600.13 of this chapter except for that which has been iodinated with radioactive iodine. Retention samples of Antibody to Hepatitis B Surface Antigen iodinated with  $^{125}\text{I}$  shall consist of

### 21 CFR Ch. I (4-1-08 Edition)

a minimum of two complete finished packages of each lot of the diagnostic test kit and shall be retained for a period of at least 90 days from the date of manufacture.

[38 FR 32098, Nov. 20, 1973, as amended at 40 FR 29711, July 15, 1975; 46 FR 36134, July 14, 1981; 49 FR 1684, Jan. 13, 1984]

#### § 660.3 Reference panel.

A Reference Hepatitis B Surface Antigen Panel shall be obtained from the Center for Biologics Evaluation and Research (HFM-407) (see mailing addresses in § 600.2 of this chapter) and shall be used for determining the potency and specificity of Antibody to Hepatitis B Surface Antigen.

[40 FR 29711, July 15, 1975, as amended at 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990; 70 FR 14985, Mar. 24, 2005]

#### § 660.4 Potency test.

To be satisfactory for release, each filling of Antibody to Hepatitis B Surface Antigen shall be tested against the Reference Hepatitis B Surface Antigen Panel and shall be sufficiently potent to detect the antigen in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package insert.

[40 FR 29711, July 15, 1975]

#### § 660.5 Specificity.

Each filling of the product shall be specific for antibody to hepatitis B surface antigen, as determined by specificity tests found acceptable by the Director, Center for Biologics Evaluation and Research.

[40 FR 29712, July 15, 1975, as amended at 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

#### § 660.6 Samples; protocols; official release.

(a) *Samples.* (1) For the purposes of this section, a sample of product not iodinated with  $^{125}\text{I}$  means a sample from each filling of each lot packaged as for distribution, including all ancillary reagents and materials; and a sample of product iodinated with  $^{125}\text{I}$  means a sample from each lot of diagnostic test kits in a finished package, including all ancillary reagents and materials.