

(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