Food and Drug Administration, HHS

§ 660.6 Samples; protocols; official release.

(a) Samples. (1) For the purposes of this section, a sample of product not iodinated with ¹²⁵I 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 ¹²⁵I means a sample from each lot of diagnostic test kits in a finished package, including all ancillary reagents and materials.


§ 660.7 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.


§ 660.8 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]

§ 660.9 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]

§ 660.10 Samples; protocols; official release.