Food and Drug Administration, HHS

§ 660.46 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 or unlyophilized HBsAg-coated red blood cells means a sample from each lot of diagnostic test kits in a finished package, including all ancillary reagents and materials.

(2) Unless the Director, Center for Biologics Evaluation and Research, determines that the reliability and consistency of the finished product can be assured with a smaller quantity of sample or no sample and specifically reduces or eliminates the required quantity of sample, each manufacturer shall submit the following samples to the Director, Center for Biologics Evaluation and Research (see mailing addresses in §600.2 of this chapter), within 5 working days after the manufacturer has satisfactorily completed all tests on the samples:
§ 660.50 Anti-Human Globulin

(a) Proper name and definition. The proper name of this product shall be Anti-Human Globulin which shall consist of one or more antiglobulin antibodies identified in §660.55(d).

(b) Source. The source of this product shall be either serum from animals immunized with one or more human serum globulins or protein-rich fluids derived from stable immunoglobulin-secreting cell lines maintained either in tissue cultures or in secondary hosts.

§ 660.51 Processing.

(a) Processing method. (1) The processing method shall be one that has been shown to yield consistently a specific, potent final product, free of properties that would adversely affect the product for its intended use throughout its dating period.

(2) Anti-IgG, –C3d (polyspecific) reagents and anti-IgG products may be colored green.

(3) Only that material which has been fully processed, thoroughly mixed in a single vessel, and filtered shall constitute a lot. Each lot shall be identified by a lot number.

(4) A lot may be subdivided into sublots which shall be identified by the lot number to which has been added a distinctive prefix or suffix. If lots are to be subdivided, the manufacturer...