

shall include this information in the license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

(b) *Final containers and dropper assemblies.* (1) Final containers and dropper assemblies shall be clean.

(2) Final containers and dropper pipettes shall be colorless and sufficiently transparent to permit observation of the contents for presence of particulate matter or increased turbidity.

(c) *Date of manufacture.* The date of manufacture shall be the date the manufacturer begins the last entire group of potency tests.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 65 FR 77499, Dec. 12, 2000; 67 FR 9587, Mar. 4, 2002]

§ 660.52 Reference preparations.

Reference Anti-Human Globulin preparations 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 as described in the accompanying package insert for determining the potency of Anti-Human Globulin.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11015, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

§ 660.53 Controls for serological procedures.

Red blood cells sensitized with complement shall be tested with appropriate positive and negative control antisera. All tests shall be performed in accordance with serological testing procedures approved by the Director, Center for Biologics Evaluation and Research.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

§ 660.54 Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

The following tests shall be performed using test procedures approved by the Director, Center for Biologics Evaluation and Research:

(a) Potency tests for determining anti-IgG and anti-complement activity.

(b) Specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

§ 660.55 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following requirements shall be met:

(a) *Final container label*—(1) *Color coding.* The main panel of the final container label of all Anti-IgG, -C3d (polyspecific) reagents shall be white or colorless and printing shall be solid dark contrasting lettering. The main panel of the final container label of all other Anti-Human Globulin reagents shall be black with solid white lettering. A logo or company name may be placed on the final container label, however, the logo or company name shall be located along the bottom or end of the label, outside of the main panel.

(2) *Required information.* The proper name “Anti-Human Globulin” need not appear on the final container label provided the final container is distributed in a package and the package label bears the proper name. The final container label shall bear the following information:

(i) Name of the antibody or antibodies present as set forth in paragraph (d) of this section. Anti-Human Globulin may contain one or more antibodies to either immunoglobulins or complement components but the name of each significant antibody must appear on the final container label (e.g., anti-C3b, -C3d, -C4d). The final container labels of polyspecific Anti-Human Globulin are not required to identify antibody specificities other than anti-IgG and anti-C3d but the reactivity of the Anti-Human Globulin shall be accurately described in the package insert.

(ii) Name, address, and license number of the manufacturer.

- (iii) Lot number, including any subplot designations.
- (iv) Expiration date.
- (v) Source of the product.
- (vi) Recommended storage temperature in degrees Celsius.
- (vii) Volume of product.
- (viii) Appropriate cautionary statement if the Anti-Human Globulin is not polyspecific. For example, “DOES NOT CONTAIN ANTIBODIES TO IMMUNOGLOBULINS” or “DOES NOT CONTAIN ANTIBODIES TO COMPLEMENT COMPONENTS.”
- (ix) If the final container is not enclosed in a package, all items required for a package label shall appear on the container label.

(3) *Lettering size.* The type size for the designation of the specific antibody on the label of a final container shall be not less than 12 point, unless otherwise approved by the Director, Center for Biologics Evaluation and Research. The prefix anti- and other parts of the name such as polyspecific may appear in smaller type.

(4) *Visual inspection.* When the label has been affixed to the final container, a sufficient area of the container shall remain uncovered for its full length or for no less than 5 millimeters of the lower circumference to permit inspection of the contents.

(b) *Package label.* The following items shall appear either on the package label or on the final container label if see-through packaging is used:

- (1) Proper name of the product, and the name of the antibody or antibodies as listed in paragraph (d) of this section.
- (2) Name, address (including zip code), and license number of the manufacturer.
- (3) Lot number, including any subplot designations.
- (4) Expiration date.
- (5) Preservative(s) used and its concentration.
- (6) Number of containers, if more than one.
- (7) Recommended storage temperature in degrees Celsius.
- (8) Source of the product.
- (9) Reference to enclosed package insert.
- (10) The statement: “For In Vitro Diagnostic Use.”

(11) The statement: “Meets FDA Potency Requirements.”

(12) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, that may indicate possible deterioration of the product.

(13) Appropriate cautions.

(c) *Package insert.* Each final container of Anti-Human Globulin shall be accompanied by a package insert meeting the requirements of §809.10 of this chapter. If two or more final containers requiring identical package inserts are placed in a single package, only one package insert per package is required.

(d) *Names of antibodies.*

Antibody designation on container label	Definition
(1) Anti-IgG, -C3d; Polyspecific.	Contains anti-IgG and anti-C3d (may contain other anticomplement and anti-immunoglobulin antibodies).
(2) Anti-IgG	Contains anti-IgG with no anticomplement activity (not necessarily gamma chain specific).
(3) Anti-IgG; heavy chains.	Contains only antibodies reactive against human gamma chains.
(4) Anti-C3b	Contains only C3b antibodies with no anti-immunoglobulin activity. Note: The antibody produced in response to immunization is usually directed against the antigenic determinant which is located in the C3c subunit; some persons have called this antibody “anti-C3c.” In product labeling, this antibody should be designated anti-C3b.
(5) Anti-C3d	Contains only C3d antibodies with no anti-immunoglobulin activity.
(6) Anti-C4b	Contains only C4b antibodies with no anti-immunoglobulin activity.
(7) Anti-C4d	Contains only C4d antibodies with no anti-immunoglobulin activity.

Anti-Human Globulin preparations may contain one or more of the antibody specificities listed in this paragraph as described in paragraph (a)(2)(i) of this section.

[50 FR 5579, Feb. 11, 1985; 50 FR 9800, Mar. 12, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

- Sec. 680.1 Allergenic Products.
- 680.2 Manufacture of Allergenic Products.
- 680.3 Tests.