

**§ 660.30**

**21 CFR Ch. I (4–1–08 Edition)**

the contents. The label on a final product container for antibodies Anti-c, Anti-k, or Anti-s shall display a bar immediately over the specificity letter used in the name, i.e., Anti- $\bar{c}$ , Anti- $\bar{k}$ , or Anti- $\bar{s}$ .

(b) *Package label.* The following information shall appear either on the package label or on the final container label if it is visible within the package.

- (1) Proper name of the product.
- (2) Name of the antibody or antibodies present as set forth in paragraph (d) of this section.
- (3) Name, address (including ZIP Code), and license number of the manufacturer.
- (4) Lot number, including subplot designations.
- (5) Expiration date.
- (6) Preservative used and its concentration.
- (7) Number of containers, if more than one.
- (8) Volume or equivalent volume for dried products when reconstituted, and precautions for adequate mixing when reconstituting.
- (9) Recommended storage temperature in degrees Celsius.
- (10) Source of the product if other than human serum or plasma.
- (11) Reference to enclosed package insert.
- (12) If a dried product, a statement indicating the period within which the product may be used after reconstitution.

(13) The statement: “FOR IN VITRO DIAGNOSTIC USE.”

(14) The statement: “MEETS FDA POTENCY REQUIREMENTS.”

(15) If human blood was used in manufacturing the product, the statement: “CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.”

(16) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, pre-

cipitate, that may indicate possible deterioration of the product.

(c) *Package insert.* Each final container of Blood Grouping Reagent shall be accompanied by a package insert meeting the requirements of § 809.10. 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.*

BLOOD GROUP DESIGNATION FOR CONTAINER LABEL

Anti-A	Anti-Jk <sup>b</sup>
Anti-A <sub>1</sub>	Anti-Js <sup>a</sup>
Anti-A, B	Anti-Js <sup>b</sup>
Anti-A and B	Anti-K
Anti-B	Anti- $\bar{k}$
Anti-C	Anti-Kp <sup>a</sup>
Anti-C <sup>w</sup>	Anti-Kp <sup>b</sup>
Anti- $\bar{c}$	Anti-Le <sup>a</sup>
Anti-CD	Anti-Le <sup>b</sup>
Anti-CDE	Anti-Lu <sup>a</sup>
Anti-Co <sup>b</sup>	Anti-Lu <sup>b</sup>
Anti-D	Anti-M
Anti-DE	Anti-M <sup>s</sup>
Anti-Di <sup>a</sup>	Anti-N
Anti-E	Anti-P <sub>1</sub>
Anti-e	Anti-S
Anti-Fy <sup>a</sup>	Anti- $\bar{s}$
Anti-Fy <sup>b</sup>	Anti-U
Anti-I	Anti-Wr <sup>a</sup>
Anti-Jk <sup>a</sup>	Anti-Xg <sup>a</sup>

[53 FR 12764, Apr. 19, 1988, as amended at 59 FR 23637, May 6, 1994; 67 FR 9587, Mar. 4, 2002; 70 FR 14985, Mar. 24, 2005]

**Subpart D—Reagent Red Blood Cells**

SOURCE: 52 FR 37450, Oct. 7, 1987, unless otherwise noted.

**§ 660.30 Reagent Red Blood Cells.**

(a) *Proper name and definition.* The proper name of the product shall be Reagent Red Blood Cells, which shall consist of a preparation of human red blood cells used to detect or identify human blood-group antibodies.

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32 of this chapter, or from umbilical cord cells which shall be collected and prepared according to

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the manufacturer's biologics license application.

[52 FR 37450, Oct. 7, 1987, as amended at 64 FR 56454, Oct. 20, 1999]

### § 660.31 Suitability of the donor.

Donors of peripheral blood for Reagent Red Blood Cells shall meet the criteria for donor suitability under § 640.3 of this chapter, except that paragraphs (b)(5) and (6), (d), and (e) of § 640.3 shall not apply.

### § 660.32 Collection of source material.

Blood for Reagent Red Blood Cells from donors of peripheral blood shall be collected as prescribed under § 640.4 of this chapter, except that paragraphs (c), (d), (g), and (h) of § 640.4 shall not apply.

### § 660.33 Testing of source material.

Except as provided in this section, a sample of each blood incorporated into the Reagent Red Blood Cell product shall be individually tested, with no fewer than two donor sources of each antibody specificity employed, to confirm the identification of all blood group antigens specified in the labeling as present or absent. The manufacturer shall perform at least one of the required tests for each factor. The Reagent Red Blood Cell product may be tested with a single donor source of antibody specificity if only one source of antibody is available, and the Director, Center for Biologics Evaluation and Research, has approved the use of a single donor source of antiserum. Each of these tests shall be conducted and interpreted independently, and any discrepancy between the results of these two tests shall be resolved by testing with at least one additional antiserum before concluding that the antigen is present or absent. Where fewer than three donor sources of an antibody specificity are available, test discrepancies shall be resolved in accordance with the manufacturer's biologics license application. Group O Reagent Red Blood Cells used in the detection or identification of unexpected antibodies shall include at least the following common antigens in each lot of the product: D, C, E,  $\bar{c}$ , e, K,  $\bar{k}$ , Fy<sup>a</sup>,

Fy<sup>b</sup>, Jk<sup>a</sup>, Jk<sup>b</sup>, Le<sup>a</sup>, Le<sup>b</sup>, P<sub>1</sub>, M, N, S, and  $\bar{s}$ .

[52 FR 37450, Oct. 7, 1987, as amended at 55 FR 11013, Mar. 26, 1990; 64 FR 56454, Oct. 20, 1999]

### § 660.34 Processing.

(a) *Processing method.* The processing method shall be one that has been shown to yield consistently a product that is capable of detecting, throughout the dating period, alloantibodies corresponding to all required blood group antigens specified in the labeling as present.

(b) *Products prepared from pooled red blood cells.* If the product is recommended for the detection of unexpected antibodies, the pool shall be prepared by combining equal amounts of cells from no more than two donors. Umbilical cord cells are exempt from this requirement. Pooled cells shall not be recommended for pretransfusion tests, done in lieu of a major cross-match, to detect unexpected antibodies in patients' samples.

(c) *Absence of antibodies.* Each lot of final product shall be free of demonstrable antibodies, including anti-A and anti-B, unless the package insert and container label include instructions to wash the cells before use. The final product shall also be direct antiglobulin test negative when tested with polyspecific anti-human globulin.

(d) *Final container.* The final containers used for each lot of product shall be clean and shall permit observation of the contents for hemolysis or a change in color. The final container label, container cap, and dropper bulb of a Reagent Red Blood Cell product may be color-coded with a visual match to a specific color approved by the Director, Center for Biologics Evaluation and Research.

(e) *Date of manufacture.* The date of manufacture of the product shall be the date that the blood is withdrawn from the donor or obtained from umbilical cords. The period during which the reagent red blood cell source material is kept by the manufacturer in storage in a frozen state at  $-65^{\circ}\text{C}$  or colder is excluded from the dating period. If the product consists of red blood cells from two or more donors, the date of manufacture of the final product shall be the date of withdrawal of blood from the