

§ 660.26

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other values are approved by the Director, Center for Biologics Evaluation and Research.

(1) For Anti-K, Anti-k̄, Anti-Jk^a, Anti-Fy^a, Anti-C^w, at least 1+ reaction with a 1:8 dilution of the reagent.

(2) For Anti-S, Anti-s̄, Anti-P₁, Anti-M, Anti-I, Anti-e (saline), Anti-c̄ (saline), and Anti-A₁, at least 1+ reaction with a 1:4 dilution of the reagent.

(3) For Anti-U, Anti-Kp^a, Anti-Kp^b, Anti-Js^a, Anti-Js^b, Anti-Fy^b, Anti-N, Anti-Le^a, Anti-Le^b, Anti-Lu^a, Anti-Lu^b, Anti-Di^a, Anti-M^g, Anti-Jk^b, Anti-Co^b, Anti-Wr^a, and Anti-Xg^a, at least 2+ reaction with undiluted reagent.

(b) *Products recommended for slide tests or microplate techniques.* Blood Grouping Reagent recommended for slide test methods or microplate techniques shall produce clearly positive macroscopic results when both undiluted reagent and reagent diluted with an equal volume of diluent are tested by all methods recommended in the manufacturer's package insert using red blood cells showing heterozygous or diminished expression of the corresponding antigen. The dilution shall be made with an equal volume of compatible serum or approved diluent.

(c) *Products recommended for use in an automated system.* The manufacturer of Blood Grouping Reagent that is recommended for use in an automated system shall demonstrate that its product when used both undiluted and diluted with an equal volume of diluent satisfactorily performs when tested with cells representing heterozygous or diminished expression of the corresponding antigen.

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

§ 660.26 Specificity tests and avidity tests.

Specificity and avidity tests shall be performed using test procedures approved by the Director, Center for Biologics Evaluation and Research.

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

§ 660.28 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65

and § 809.10, and in lieu of the requirements in §§ 610.60 and 610.61, the following requirements shall be met:

(a) *Final container label*—(1) *Color coding.* The final container label of all Blood Grouping Reagents shall be completely white, except that all or a portion of the final container label of the following Blood Grouping Reagents may be color coded with the specified color which shall be a visual match to a specific color sample designated by the Director, Center for Biologics Evaluation and Research. Printing on all final container labels shall be in solid black. 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 the main panel.

Blood grouping reagent	Color of label paper
Anti-A	Blue.
Anti-B	Yellow.
Slide and rapid tube test blood grouping reagents only:	
Anti-C	Pink.
Anti-D	Gray.
Anti-E	Brown.
Anti-CDE	Orange.
Anti-c̄	Lavender.
Anti-e	Green.

(2) *Required information.* The proper name "Blood Grouping Reagent" 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.
- (ii) Name, address (including ZIP code), and license number of the manufacturer.
- (iii) Lot number, including subplot designations.
- (iv) Expiration date.
- (v) Source of product if other than human plasma or serum.
- (vi) Test method(s) recommended.
- (vii) Recommended storage temperature in degrees Celsius.
- (viii) Volume of product if a liquid, or equivalent volume for a dried product if it is to be reconstituted.
- (ix) If a dried product, to remind users to record the reconstitution date

on the label, the statement “RECONSTITUTION DATE _____, EXPIRES 1 YEAR AFTER RECONSTITUTION DATE.”

(3) *Lettering size.* The type size for the specificity of the antibody designation on the labels of a final container with a capacity of less than 5 milliliters shall be not less than 12 point. The type size for the specificity of the antibody designations on the label of a container with a capacity of 5 milliliters or more shall be not less than 18 point.

(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 no less than 5 millimeters of the lower circumference to permit inspection of 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-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, precipitate, 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 ^b
Anti-A ₁	Anti-Js ^a
Anti-A, B	Anti-Js ^b
Anti-A and B	Anti-K
Anti-B	Anti- \bar{k}
Anti-C	Anti-Kp ^a
Anti-C ^w	Anti-Kp ^b
Anti- \bar{c}	Anti-Le ^a
Anti-CD	Anti-Le ^b
Anti-CDE	Anti-Lu ^a
Anti-Co ^b	Anti-Lu ^b
Anti-D	Anti-M
Anti-DE	Anti-M ^s
Anti-Di ^a	Anti-N
Anti-E	Anti-P ₁
Anti-e	Anti-S
Anti-Fy ^a	Anti- \bar{s}
Anti-Fy ^b	Anti-U
Anti-I	Anti-Wr ^a
Anti-Jk ^a	Anti-Xg ^a

[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]