

§ 660.26

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

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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- \bar{c}	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 sublot 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