§660.22 Potency requirements with reference preparations.

(a) Potency requirements. Products for which reference Blood Grouping Reagents are available shall have a potency titer value at least equal to that of the reference preparation.

(b) Reference preparations. Reference Blood Grouping Reagents 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 Blood Grouping Reagents.

§660.25 Potency tests without reference preparations.

Products for which Reference Blood Grouping Reagents are not available shall be tested for potency by a method approved by the Director, Center for Biologics Evaluation and Research.

(a) Potency requirements. Blood Grouping Reagents recommended for the test tube methods, including the indirect antiglobulin tests, shall have the following potency titer values, unless other values are approved by the Director, Center for Biologics Evaluation and Research.

1. For Anti-K, Anti-k, Anti-Jk\(^a\), Anti-Fy\(^a\), Anti-C\(^w\), at least 1+ reaction with a 1:3 dilution of the reagent.
2. For Anti-S, Anti-s, Anti-P\(^1\), Anti-M, Anti-I, Anti-e (saline), Anti-c (saline), and Anti-A\(_1\), 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\(^a\), 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 the 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.

§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.

§660.28 Labeling.

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