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Certificate of Analysis

This is to certify that the product listed hereunder has been manufactured and tested by Immucor, Inc., of Norcross, Georgia. The product is licensed for manufacture by the Food and Drug Administration of the United States Department of Health and Human Services under License No. 886. The product listed has been tested in accordance with current FDA requirements for the product in question, and has been found to meet all specifications.

Product: Blood Grouping Reagent (Murine Monoclonal) by Slide, Tube and Microplate Tests
Anti-A, Series 1 ☐ **Anti-B, Series 3** ☒ **Anti-A,B, Series 1** ☐

Catalog No. 0006406 / 10 x 10 mL

Lot No. 203691 Note: Any numbers following a dash after the lot number denote only the vialing sequence. These are not separate lot numbers.

Expiration date: 2019-02-16 **Date of manufacture:** 2017-03-07

Chemical Composition: Monoclonal antibodies secreted by murine hydridomas (Anti-A Birma-1; Anti-B LB2; Anti-A,B blend of Birma-1, ES4 and ES15) grown in fluid culture, formulated in a buffered saline solution containing bovine albumin (without stabilizers), ethylenediamine tetraacetate (EDTA), and ingredients to facilitate the resuspension of red cell buttons following centrifugation. Sodium azide is present as a preservative at a concentration of 0.1%. In addition, Anti-A contains FD and C blue #1 and Anti-B contains Naphthol Yellow as coloring agents.

Viral Marker Testing: Not applicable. Product contains no human source material.

Potency:

Requirement	Phenotype	Results
Must equal or exceed the potency of the corresponding FDA reference preparation.	A_1	Not tested
	A_2	Not tested
	A_1B	1024 / pass
	A_2B	1024 / pass
	B	1024 / pass

Reactivity in Microplates:

Requirement	Phenotype	Results
Must show acceptable reactivity when tested by the recommended microplate procedure (undiluted and diluted 1+1)	A_1	Not Tested
	A_2	Not Tested
	A_1B	Pass
	A_2B	Pass
	B	Pass
	A_x	Not Tested

Avidity:

Requirement	Phenotype	Results
When tested by the recommended slide test procedure, (undiluted and diluted 1+1 with human serum) agglutination must begin within 1 minute.	A_1	Not Tested
	A_2	Not Tested
	A_1B	Pass
	A_2B	Pass
	B	Pass

Specificity:

Requirement	Confirmed
Absence of rouleaux, hemolysis; no reactivity with red blood cells possessing antigens having incidence of 1% or greater in the U.S. population.	☒

Approved for Release: All specifications met; labeling checked and confirmed. **Released** ☐

QC Reviewed By/Date: 17 MAR 2017 Approved By/Date: [illegible] 04 APR 2017