Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30091-5625
Tel: (770) 441-2051 Toll-free: (800) 510-5110
FAX: (770) 441-3807
Web site http://www.immucor.com

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: Gamma-clone® Blood Grouping Reagent (Murine Monoclonal)
Anti-Le(a) ☐ Anti-Le(b) ☒

Catalog No. 0004864 / 1 x 5 mL

Lot No. 992015 Note: Any numbers following a dash after the lot number denote only the vialing sequence. These are not separate lot numbers.

Expiration date: 24 January 2019 **Date of manufacture:** 24 January 2017

Chemical Composition: Monoclonal antibodies secreted by murine hybridomas (Anti-Le^a GAMA701, Anti-Le^b GAMA704). The final formulation includes a diluent containing phosphate-buffered saline and bovine albumin to yield a maximum total protein concentration that does not exceed 6%, with a macromolecular compound to potentiate and accelerate the specific agglutination reaction. Sodium azide is present as a preservative at a concentration of 0.1%.

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

Potency:

Requirement	Phenotype	Results
A titer of 8 or greater when tested by a saline tube test procedure.	O Le^a +	16 / pass
	O Le^b +	16 / 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: [signature] 08 MAR 2017 Approved By/Date: [signature] 08 MAR 2017