

Immucor, Inc.
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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: Reagent Red Blood Cells for ABO Serum Grouping

Referencells - 2 vial set

Catalog Nos. 0002345 / 2 x 10 mL

Kit Lot No. 110347

Component Lot Nos. A₁ 111171

A₂ B 113171

B

O

Expiration date: 2018-02-09 **Date of manufacture:** 2017-12-04

Chemical Composition: Pooled C-D-E- human red blood cells suspended to 2-4% concentration in buffered preservative solution containing EDTA, Neomycin Sulfate 0.1 mg/mL, Chloramphenicol 0.25 mg/mL, and Gentamycin Sulfate 0.05 mg/mL.

Viral Marker Testing:

	Requirement	Non-reactive
Source material nonreactive for antibodies to human immunodeficiency virus types 1 and 2 (anti-HIV) and human hepatitis C virus (Anti-HCV), and hepatitis B surface antigen (HBsAg); and nonreactive for HIV-1 RNA and HCV RNA by NAT using FDA-licensed tests and nonreactive for serologic test for syphilis (STS).	HBsAg	<input checked="" type="checkbox"/>
	Anti-HCV	<input checked="" type="checkbox"/>
	Anti-HIV	<input checked="" type="checkbox"/>
	HIV-1 RNA	<input checked="" type="checkbox"/>
	HCV RNA	<input checked="" type="checkbox"/>
	STS	<input checked="" type="checkbox"/>

Antigens represented:

	Requirement	Confirmed
All cells are C-D-E-. No selection for antigens other than ABO.		<input checked="" type="checkbox"/>

Identity testing:

Individual products tested for identity as labeled.		<input checked="" type="checkbox"/>
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Approved for Release:

All specifications met; labeling checked and confirmed.		<input checked="" type="checkbox"/>
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QC Reviewed by/Date: S. Chodasara / 26 DEC 2017 Approved by/Date: Beise / 27 DEC 2017