

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 Detection of Unexpected Antibodies

Catalog Nos. Hemantigen (Pooled Cells) ☐ Panoscreen I and II ☐ Panoscreen I, II, and III ☒
0002377 / 3 x 10 mL

Lot No. 22082

Expiration date: 2023-08-04 **Date of manufacture:** 2023-05-29

Chemical Composition: Group O human red blood cells suspended to 2-4% concentration in buffered preservative solution containing 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
D, C, E, c, e, K, k, Fy ^a , Fy ^b , Jk ^a , Jk ^b , Le ^a , Le ^b , P ₁ , M, N, S, s		<input checked="" type="checkbox"/>

Identity testing: Individual products tested for identity as labeled. ☒

Approved for Release: All specifications met; labeling checked and confirmed. ☒

DocuSigned by Jeanne Mutua
 I am the author of this document
21-Jun-2023 | 12:35:24 PM EDT
59D00F48DF0D429AB3D894F7806CBA14

DocuSigned by George Gyimah
 I approve this document
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QC Reviewed by/Date: _____ Approved by/Date: _____