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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 listed has been tested in accordance with current requirements for the product in question, and has been found to meet all specifications.

Product: Checkcell ☒ Checkcell (Weak) ☐ Complement Control Cells ☐
Catalog Nos. 0002225 / 3 x 10 mL
Lot No. 22554
Expiration date: 2023-08-04 **Date of manufacture:** 2023-05-29

Chemical Composition: Checkcell: A 4-6% suspension of group O pooled human red blood cells sensitized with an IgG antibody.
Checkcell (Weak): A 2-3% suspension of group O pooled human red blood cells sensitized with an IgG antibody.
Complement Control Cells: A 2-4% suspension of pooled human red blood cells sensitized with human complement.
These red blood cells are suspended 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"/>

Identity testing: Product 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 | 11:35:06 AM EDT
59D00F48DF0D429AB3D894F7808CBA14

DocuSigned by George Gyimah
 I approve this document
21-Jun-2023 | 6:46:42 PM EDT
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QC Reviewed by/Date: _____ Approved by/Date: _____