

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

Product: corQC EXTEND **corQC EXTEND 1, 2, and 3**

Catalog Nos. 0002417 / 3 x 5 mL

Kit Lot No. 913143

Component Lot Nos.

Std	1	127153
1	2	128153
2	3	126153
3		
4		

Expiration date: 2018-01-19 **Date of manufacture:** 2017-11-13

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 Ag <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. **Released**

QC Reviewed by/Date: Quhodanara / 05 DEC 2017 Approved by/Date: Belind / 06 DEC 2017