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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 Test System
 1. corQC Reagent Cells Component Lot No. 50136L
 2. corQC Reagent Antiserum Component Lot No. 134040

Catalog Nos. 0002410 / 2 x 11.5 mL

Lot No. 50136L

Expiration date: 2018-02-16 **Date of manufacture:** 2017-12-11

Chemical Composition: Group AB, D+ human red blood cells. These red cells are suspended to 2-4% concentration in buffered preservative solution containing adenosine and adenine (to retard hemolysis and loss of antigenicity during the dating period), Neomycin Sulfate 0.1 mg/mL, Chloramphenicol 0.25 mg/mL, and Gentamycin Sulfate 0.05 mg/mL.

Reagent antiserum consists of a blend of monoclonal ABO antibodies with human or monoclonal sera containing weakly reactive antibodies that will react with all antigens required to be represented on reagent red blood cells used for the detection of unexpected antibodies. The reagent serum is diluted in a sodium chloride solution to which bovine albumin may have been added.

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"/>

Reactivity:	Requirement	Confirmed
	Red blood cell component confirmed to be of stated ABO/Rh phenotypes.	<input checked="" type="checkbox"/>
	Antibody reagent reacts with reverse grouping cells (A ₁ , A ₂ , and B) by a saline-agglutinating test procedure, and reacts with group O screening cells by the indirect antiglobulin test.	<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: Frank Hugg 02 JAN 2018 Approved by/Date: [Signature] 02 JAN 2018