



CERTIFICATE OF ANALYSIS

Bioprofile Flex IgG2 Reagent Pack
Lot Number 22158037

Part Number 48541
Exp Date 2023-05

Soln C	L/N	22124021		
		<u>Spec</u>	<u>Result</u>	
NaOCI%	0.70 - 0.90	Pass		

Soln B	L/N	22124028		
		<u>Spec</u>	<u>Result</u>	
pH	5.30 - 5.35	Pass		

IgG Rgt	L/N	22120004		
		<u>Spec</u>	<u>Result</u>	
Binding Soln	N/A	Pass		

IgG Std	L/N	22131006		
		<u>Spec</u>	<u>Result</u>	
5.0 mg/mL IgG	N/A	Present		

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. The following analytes are traceable to NIST SRM Materials: pH.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector
Title

7/8/2022
Date