



CERTIFICATE OF ANALYSIS

Bioprofile 300 A Reagent Pack
Lot Number 425779

Part Number 33132
Exp Date 2025-06-30

Std A L/N	24257079		Std B L/N	24257079		Std H L/N	24257079	
	<u>Spec</u>	<u>Result</u>		<u>Spec</u>	<u>Result</u>		<u>Spec</u>	<u>Result</u>
Na mmol/L	138.6 - 141.4	Pass	K mmol/L	9.9 - 10.1	Pass	Ammonium Salts	N/A	Present
K mmol/L	3.96 - 4.04	Pass	NH4 mmol/L	9.9 - 10.1	Pass			
NH4 mmol/L	1.98 - 2.02	Pass	pH @ 37C	6.847 - 6.853	Pass			
pH @ 37C	7.377 - 7.383	Pass	Gluc g/L	9.50 - 10.50	Pass			
Gluc g/L	1.80 - 2.20	Pass	Lac g/L	2.75 - 3.25	Pass			
Lac g/L	0.80 - 1.20	Pass	Ace mmol/L	85.0 - 115.0	Pass			
Ace mmol/L	18.0 - 22.0	Pass	Phos	3.60 - 4.40	Pass			
Phos	0.80 - 1.20	Pass						

Flush L/N	24257079			
	<u>Spec</u>	<u>Result</u>		
Aqueous Salt Solution	N/A	Present		

Reference L/N	24257079			
	<u>Spec</u>	<u>Result</u>		
KCl mol/L	1.8 - 2.2	Pass		

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: Na, K, NH4, pH, Gluc, Lac, KCl.

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

Haneen Aldarwish

Approval

QC Inspector
Title

10/18/2024
Date