



CERTIFICATE OF ANALYSIS

Bioprofile 300 B Reagent Pack
Lot Number 412448

Part Number 33133
Exp Date 2025-02-28

Std A L/N	24124048		Std B L/N	24124048	
	<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
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 @ 37.0	6.847 - 6.853	Pass
pH @ 37.0	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	Gly g/L	4.50 - 5.50	Pass
Gly g/L	2.25 - 2.90	Pass			

Flush L/N 24124048

	<u>Spec</u>	<u>Result</u>
Aqueous Salt solution	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: Na, K, NH4, pH, Gluc, Lac.

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

Approval

QC inspector

Title

6/20/2024

Date