



CERTIFICATE OF ANALYSIS

Bioprofile 100 Plus Reagent Pack
Lot Number 425532

Part Number 38291
Exp Date 2025-11-30

Std A	L/N	24240024		Std B	L/N	24236075		Std C	L/N	24239027		
			<u>Spec</u>	<u>Result</u>			<u>Spec</u>	<u>Result</u>			<u>Spec</u>	<u>Result</u>
pH @ 37C			7.381 - 7.387	Pass	pH @ 37C		6.837 - 6.843	Pass	Na mmol/L		139 - 141	Pass
Lac g/L			4.5 - 5.5	Pass					K mmol/L		3.97 - 4.03	Pass
Glu mmol/L			4.5 - 5.5	Pass					Lac g/L		0.9 - 1.1	Pass
Gluc g/L			14.3 - 15.7	Pass					Gluc g/L		0.9 - 1.1	Pass
									NH4 mmol/L		0.99 - 1.01	Pass
									Gln mmol/L		0.90 - 1.10	Pass
									Glu mmol/L		0.4 - 0.6	Pass
Std D	L/N	24239028		Flush	L/N	24239026		Reference	L/N	24235064		
			<u>Spec</u>	<u>Result</u>			<u>Spec</u>	<u>Result</u>			<u>Spec</u>	<u>Result</u>
Na mmol/L			74.5 - 75.5	Pass	Aqueous Salt		N/A	Present	KCl mol/L		1.8 - 2.2	Pass
K mmol/L			9.92 - 10.08	Pass	Solution							
Lac g/L			2.7 - 3.3	Pass								
Gluc g/L			4.5 - 5.5	Pass								
NH4 mmol/L			4.95 - 5.05	Pass								
Gln mmol/L			4.50 - 5.50	Pass								
Glu mmol/L			1.75 - 2.25	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: pH, Lac, Gluc, Na, K, NH4, KCl.

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

Approval

QC Inspector

Title

9/26/2024

Date