



**CERTIFICATE OF ANALYSIS**

BioProfile 400 Reagent Pack  
Lot Number 331059

Ref Number 36281  
Exp Date 2025-01-31

Std A	L/N	23291061		
			<u>Spec</u>	<u>Result</u>
pH @37C			7.381 - 7.387	Pass
Lac g/L			4.5 - 5.5	Pass
Glu mmol/L			4.5 - 5.5	Pass
Gluc g/L			14.3 - 15.7	Pass

Std B	L/N	23291065		
			<u>Spec</u>	<u>Result</u>
pH @37C			6.837 - 6.843	Pass

Std C	L/N	23290113		
			<u>Spec</u>	<u>Result</u>
Na mmol/L			139 - 141	Pass
K mmol/L			3.97 - 4.03	Pass
Lac g/L			0.9 - 1.1	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	23290114		
			<u>Spec</u>	<u>Result</u>
Na mmol/L			74.5 - 75.5	Pass
K mmol/L			9.92 - 10.08	Pass
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

Flush	L/N	23298038		
			<u>Spec</u>	<u>Result</u>
Aqueous salt Solution			N/A	Present

Reference	L/N	23289036		
			<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. All listed analytes are traceable to NIST SRM Materials.

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

Haneen Aldarwish

Approval

QC Inspector  
Title

11/14/2023  
Date