



CERTIFICATE OF ANALYSIS

BioProfile 400 Reagent Pack
Lot Number 420827

Ref Number 36281
Exp Date 2025-10-31

Std A	L/N	24193048		
		<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	24194015		
		<u>Spec</u>	<u>Result</u>	
pH @37C		6.837 - 6.843	Pass	

Std C	L/N	24193027		
		<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	24193028		
		<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	24194020		
		<u>Spec</u>	<u>Result</u>	
Aqueous salt Solution		N/A	Present	

Reference	L/N	24201057		
		<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

Approval

QC Inspector
Title

08/16/2024
Date