

nova *biomedical*

CERTIFICATE OF ANALYSIS

Bioprofile 400 Reagent Pack
Lot Number 132741

Part Number 36281
Exp Date 2023-02-28

Std A L/N 21314043			Std B L/N 21314044			Std C L/N 21308015		
	<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 21308014			Flush L/N 21322069			Reference L/N 21314053		
	<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

12/20/2021
Date