



CERTIFICATE OF ANALYSIS

Bioprofile FLEX2 Chemistry AutoQC Cartridge
Lot Number 23090014

Exp Date 2024-09-07
Date of Manufacture 2023-03-07

Ref Number 57035

Level 1 Lot #	23066038		Level 2 Lot #	23066039	
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Gln mmol/L	0.85 - 1.15	Pass	Gln mmol/L	4.60 - 5.40	Pass
Glu mmol/L	0.40 - 0.60	Pass	Glu mmol/L	2.00 - 3.00	Pass
Gluc g/L	0.85 - 1.15	Pass	Gluc g/L	12.75 - 17.25	Pass
Lac g/L	0.85 - 1.15	Pass	Lac g/L	4.5 - 5.5	Pass
NH4 mmol/L	0.60 - 1.00	Pass	NH4 mmol/L	9.25 - 10.75	Pass
Na mmol/L	70.0 - 80.0	Pass	Na mmol/L	170.0 - 190.0	Pass
K mmol/L	1.95 - 2.15	Pass	K mmol/L	9.25 - 10.75	Pass
Ca mmol/L	0.55 - 0.70	Pass	Ca mmol/L	2.80 - 3.80	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: Gluc, Lac, NH4, Na, K, Ca.

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

Haneen Aldarwish

Approval

QC Inspector
Title

5/5/2023
Date