



CERTIFICATE OF ANALYSIS

BioProfile FLEX Nutrient/Metabolite Cal Cartridge
Lot Number 22048020

Part Number 39544
Exp Date 2023-05

CAL N1 L/N 22048018

CAL N2 L/N 22048019

Nutrient Flush L/N 22048020

	<u>Spec</u>	<u>Result</u>
Gln mmol/L	0.09 - 0.11	Pass
Glu mmol/L	0.045 - 0.055	Pass
Gluc g/L	0.09 - 0.11	Pass
Lac g/L	0.09 - 0.11	Pass

	<u>Spec</u>	<u>Result</u>
Gln mmol/L	0.45 - 0.55	Pass
Glu mmol/L	0.175 - 0.225	Pass
Gluc g/L	0.45 - 0.55	Pass
Lac g/L	0.27 - 0.33	Pass

	<u>Spec</u>	<u>Result</u>
pH	6.900 - 7.100	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.

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

Approval

QC Inspector
Title

3/18/2022
Date