



CERTIFICATE OF ANALYSIS

BioProfile FLEX Nutrient/Metabolite Cal Cartridge
Lot Number 23279066

Part Number 39544
Exp Date 2025-01

CAL N1 L/N 23279070

CAL N2 L/N 23279069

Nutrient Flush L/N 23279066

| | <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

Auishi M

Approval

QC Inspector

Title

11/13/2023

Date