



CERTIFICATE OF ANALYSIS

BioProfile FLEX Gas/Electrolyte Cal Cart
Lot Number 23300020

Part Number 39543
Exp Date 2025-01

Cal A L/N 23300020

| | <u>Spec</u> | <u>Pass/Fail</u> |
|----|---------------|------------------|
| pH | 7.381 - 7.387 | Pass |

Cal B L/N 23300020

| | <u>Spec</u> | <u>Pass/Fail</u> |
|------------|---------------|------------------|
| pH | 6.837 - 6.843 | Pass |
| iCa++ (mM) | 1.97 - 2.03 | Pass |

Cal C L/N 23300020

| | <u>Spec</u> | <u>Pass/Fail</u> |
|------------|---------------|------------------|
| HCO3 (mM) | 19.6 - 20.4 | Pass |
| NH4+ (mM) | 0.99 - 1.01 | Pass |
| Na+ (mM) | 139.0 - 141.0 | Pass |
| K+ (mM) | 3.97 - 4.03 | Pass |
| iCa++ (mM) | 0.99 - 1.02 | Pass |

Cal D L/N 23300020

| | <u>Spec</u> | <u>Pass/Fail</u> |
|-----------|--------------|------------------|
| HCO3 (mM) | 39.2 - 40.8 | Pass |
| NH4+ (mM) | 4.95 - 5.05 | Pass |
| Na+ (mM) | 74.5 - 75.5 | Pass |
| K+ (mM) | 9.92 - 10.08 | Pass |

Reference L/N 23300020

| | <u>Spec</u> | <u>Pass/Fail</u> |
|---------|-------------|------------------|
| KCl (M) | 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. The following analytes are traceable to NIST SRM Materials: Na, HCO3, pH, KCl, iCa, NH4, K.

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

Approval

QC Inspector

Title

11/28/2023

Date