



CERTIFICATE OF ANALYSIS

Stat Profile CCX Calibrator Cartridge 4
Lot Number 23339045

Ref Number 37164
Exp Date 2025-05-21

Date of Manufacture 2023-11-21

UDI# (01)00385480371643(11)231121(17)250521(10)23339045

| Cal-A L/N 23331029 | | | |
|--------------------|---------------|--|------------------|
| | <u>Spec</u> | | <u>Pass/Fail</u> |
| pH @ 37C | 7.351 - 7.357 | | Pass |
| Lac mmol/L | 13.5 - 16.5 | | Pass |

| Cal-B L/N 23325045 | | | |
|--------------------|---------------|--|------------------|
| | <u>Spec</u> | | <u>Pass/Fail</u> |
| pH @ 37C | 6.822 - 6.828 | | Pass |
| Na mmol/L | 69.5 - 70.5 | | Pass |
| K mmol/L | 9.9 - 10.1 | | Pass |
| Cl mmol/L | 39.7 - 40.3 | | Pass |
| Ca mmol/L | 1.97 - 2.03 | | Pass |
| Mg mmol/L | 1.48 - 1.52 | | Pass |

| Cal-C L/N 23325044 | | | |
|--------------------|---------------|--|------------------|
| | <u>Spec</u> | | <u>Pass/Fail</u> |
| Na mmol/L | 139.0 - 141.0 | | Pass |
| K mmol/L | 3.97 - 4.03 | | Pass |
| Cl mmol/L | 118.0 - 120.0 | | Pass |
| Ca mmol/L | 0.99 - 1.02 | | Pass |
| Mg mmol/L | 0.49 - 0.51 | | Pass |
| Glu mg/dL | 78.8 - 81.2 | | Pass |
| Lac mmol/L | 1.8 - 2.2 | | Pass |
| BUN mg/dL | 9.9 - 10.1 | | Pass |
| HCO3 mmol/L | 18.43 - 19.19 | | Pass |

| Cal-D L/N 23325043 | | | |
|--------------------|---------------|--|------------------|
| | <u>Spec</u> | | <u>Pass/Fail</u> |
| Glu mg/dL | 197 - 203 | | Pass |
| Lac mmol/L | 5.5 - 6.5 | | Pass |
| BUN mg/dL | 49.4 - 50.6 | | Pass |
| HCO3 mmol/L | 37.05 - 38.57 | | Pass |

| Flush L/N 23333049 | | | |
|--------------------|-------------|--|------------------|
| | <u>Spec</u> | | <u>Pass/Fail</u> |
| Aqueous | | | |
| Salt | N/A | | Present |
| Solution | | | |

| Reference L/N 23325050 | | | |
|------------------------|-------------|--|------------------|
| | <u>Spec</u> | | <u>Pass/Fail</u> |
| KCl mol/L | 1.8 - 2.2 | | Pass |

This certifies that this product was manufactured and tested at Nova BiomedCal-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. All listed analytes are traceable to NIST SRM Materials.

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

Haneen Aldarwish

Approval

QC Inspector

Title

12/15/2023

Date