



CERTIFICATE OF ANALYSIS

Stat Profile CCX Calibrator Cartridge 4
Lot Number 23216012

Ref Number 37164
Exp Date 2024-12-19

Date of Manufacture 2023-06-19

UDI# (01)00385480371643(11)230619(17)241219(10)23216012

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|--------------------|---------------|------------------|--------------------|---------------|------------------|------------------------|---------------|------------------|
| Cal-A L/N 23170052 | | | Cal-B L/N 23174046 | | | Cal-C L/N 23173090 | | |
| | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| pH @ 37C | 7.351 - 7.357 | Pass | pH @ 37C | 6.822 - 6.828 | Pass | Na mmol/L | 139.0 - 141.0 | Pass |
| Lac mmol/L | 13.5 - 16.5 | Pass | Na mmol/L | 69.5 - 70.5 | Pass | K mmol/L | 3.97 - 4.03 | Pass |
| | | | K mmol/L | 9.9 - 10.1 | Pass | Cl mmol/L | 118.0 - 120.0 | Pass |
| | | | Cl mmol/L | 39.7 - 40.3 | Pass | Ca mmol/L | 0.99 - 1.02 | Pass |
| | | | Ca mmol/L | 1.97 - 2.03 | Pass | Mg mmol/L | 0.49 - 0.51 | Pass |
| | | | Mg mmol/L | 1.48 - 1.52 | 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 23172066 | | | Flush L/N 23173024 | | | Reference L/N 23170050 | | |
| | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| Glu mg/dL | 197 - 203 | Pass | Aqueous | | | KCl mol/L | 1.8 - 2.2 | Pass |
| Lac mmol/L | 5.5 - 6.5 | Pass | Salt | N/A | Present | | | |
| BUN mg/dL | 49.4 - 50.6 | Pass | Solution | | | | | |
| HCO3 mmol/L | 37.1 - 38.57 | 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

Awishi M
Approval

QC Inspector
Title

8/7/2023
Date