



## CERTIFICATE OF ANALYSIS

Stat Profile pHox Ultra/CCX Calibrator Cartridge 1  
Lot Number 25094025

Ref Number 48834  
Exp Date 2026-09-13

Date of Manufacture 2025-03-13

UDI# (01)00385480488341(11)250313(17)260913(10)25094025

| Cal-A L/N  | 25073016                     |
|------------|------------------------------|
|            | <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 | 25073015                     |
|-----------|------------------------------|
|           | <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   | 25073017                     |
|-------------|------------------------------|
|             | <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   | 25073018                     |
|-------------|------------------------------|
|             | <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 | 25085058                     |
|-----------|------------------------------|
|           | <u>Spec</u> <u>Pass/Fail</u> |
| Aqueous   |                              |
| Salt      | N/A Present                  |
| Solution  |                              |

| Reference L/N | 25072032                     |
|---------------|------------------------------|
|               | <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

Approval

QC Inspector  
Title

4/10/2025  
Date