



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Cal Cartridge 1 w/Creat
Lot Number 25010024

Ref Number 48836
Exp Date 2026-05-12

Date of Manufacture 2024-11-12

UDI# (01)00385480488365(11)241112(17)260512(10)25010024

Cal A L/N 24319013

| | <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 24317055

| | <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 24317056

| | <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 |
| BUN mg/dl | 9.9 - 10.1 | Pass |
| Glu mg/dl | 78.8 - 81.2 | Pass |
| Lac mmol/L | 1.8 - 2.2 | Pass |
| Ca mmol/L | 0.99 - 1.02 | Pass |
| Mg mmol/L | 0.49 - 0.51 | Pass |
| Creat mg/dl | 0.98 - 1.02 | Pass |
| HCO3 mmol/L | 18.34 - 19.08 | Pass |

Cal D L/N 24317057

| | <u>Spec</u> | <u>Pass/Fail</u> |
|-------------|---------------|------------------|
| BUN mg/dl | 49.4 - 50.6 | Pass |
| Glu mg/dl | 197 - 203 | Pass |
| Lac mmol/L | 5.5 - 6.5 | Pass |
| Creat mg/dl | 9.8 - 10.2 | Pass |
| CO3 mmol/L | 36.68 - 38.18 | Pass |

Flush L/N 24323026

| | <u>Spec</u> | <u>Result</u> |
|-----------------------|-------------|---------------|
| Aqueous Salt Solution | N/A | Present |

Reference L/N 24318031

| | <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 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. 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

1/15/2025

Date