

CERTIFICATE OF ANALYSIS

STP pHOxUltra/CCX Chemistry Controls & Performance Check Auto-Cartridge W/Creatinine

Ref Number 48928 Exp Date 2025-07-17

Lot Number 24057037

Date of Manufacture 2024-01-17

UDI# (01)00385480489287(11)240117(17)250717(10)24057037

| | Level 4 | | | Level 5 | |
|------------------|---------------|-----------|------------------|---------------|-----------|
| | <u>Spec</u> | Pass/Fail | | <u>Spec</u> | Pass/Fail |
| Na+ mmol/L | 138.6 - 141.4 | Pass | Na+ mmol/L | 113.4 - 115.6 | Pass |
| K+ mmol/L | 3.93 - 4.01 | Pass | K+ mmol/L | 6.34 - 6.46 | Pass |
| CI- mmol/L | 124.5 - 127.1 | Pass | CI- mmol/L | 95.0 - 97.0 | Pass |
| Ca++ mmol/L | 1.10 - 1.12 | Pass | Ca++ mmol/L | 1.61 - 1.65 | Pass |
| Mg++ mmol/L | 0.56 - 0.64 | Pass | Mg++ mmol/L | 1.07 - 1.19 | Pass |
| Glu mg/dL | 78 - 82 | Pass | Glu mg/dL | 274 - 286 | Pass |
| Lac mmol/L | 1.9 - 2.1 | Pass | Lac mmol/L | 7.0 - 7.2 | Pass |
| BUN mg/dL | 18.5 - 19.5 | Pass | BUN mg/dL | 54.6 - 57.4 | Pass |
| Creatinine mg/dL | 0.98 - 1.02 | Pass | Creatinine mg/dL | 6.08 - 6.32 | Pass |

Performance Check

| | <u>Spec</u> | Pass/Fail |
|------------------|-------------|-----------|
| Glu mg/dL | 700 - 1500 | Pass |
| Creatinine mg/dL | 0.80 - 1.80 | 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

Lumanu Lehter

Title

3/6/2024 Date