

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Chemistry Controls Auto-Cartridge 4/Day Lot Number 24302100

ols Ref Number 48906 Exp Date 2026-04-16 Date of Manufacture 2024-10-16 UDI# (01)00385480489065(11)241016(17)260416(10)24302100

| | Level 4 | | | Level 5 | |
|-------------|---------------|-----------|-------------|---------------|-----------|
| | <u>Spec</u> | Pass/Fail | | <u>Spec</u> | Pass/Fail |
| Na+ mmol/L | 141.8 - 144.6 | Pass | Na+ mmol/L | 115.6 - 118.0 | Pass |
| K+ mmol/L | 4.01 - 4.09 | Pass | K+ mmol/L | 6.51 - 6.65 | Pass |
| CI- mmol/L | 125.4 - 128.0 | Pass | CI- mmol/L | 95.0 - 97.0 | Pass |
| Ca++ mmol/L | 1.10 - 1.12 | Pass | Ca++ mmol/L | 1.60 - 1.64 | Pass |
| Mg++ mmol/L | 0.56 - 0.64 | Pass | Mg++ mmol/L | 1.05 - 1.17 | Pass |
| Glu mg/dL | 78 - 82 | Pass | Glu mg/dL | 274 - 286 | Pass |
| Lac mmol/L | 1.9 - 2.1 | Pass | Lac mmol/L | 7.1 - 7.3 | Pass |
| BUN mg/dL | 18.5 - 19.5 | Pass | BUN mg/dL | 54.6 - 57.4 | Pass |

Level 6

QC Performance Check

Spec Pass/Fai
Glu mg/dL 700 - 1500 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

11/5/2024 Date