

## **CERTIFICATE OF ANALYSIS**

STP pHOx Ultra/CCX Cal Cartridge 1 w/Creat Lot Number 23250012

1 w/Creat Ref Number 48836 Exp Date 2024-12-29 Date of Manufacture 2023-06-29 UDI# (01)00385480488365(11)230629(17)241229(10)23250012

Cal A L/N 23186010	Cal B L/N 23181018	Cal C L/N 23181019
<u>Spec</u> <u>Pass/Fail</u> pH @ 37C 7.351 - 7.357 Pass Lac mmol/L 13.5 - 16.5 Pass	Spec Pass/Fai   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	Spec Pass/Fail   Na mmol/L 139.0 - 141.0 Pass   K mmol/L 3.97 - 4.03 Pass   CI 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 23181020	Flush L/N 23191073	Reference L/N 23180068
Spec Pass/Fail   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   ICO3 mmol/L 36.68 - 38.18 Pass	<u>Spec Result</u> Aqueous Salt N/A Present Solution	<u>Spec Pass/Fail</u> KCI 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

Frint

Approval

QC Inspector Title

<u>9/13/2023</u> Date