

## **CERTIFICATE OF ANALYSIS**

STP pHOx Ultra/CCX Cal Cartridge 1 w/Creat Lot Number 23250011 Ref Number 48836 Exp Date 2024-12-29 Date of Manufacture 2023-06-29

UDI# (01)00385480488365(11)230629(17)241229(10)23250011

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	SpecPass/FailpH @ 37C6.822 - 6.828PassNa mmol/L69.5 - 70.5PassK mmol/L9.9 - 10.1PassCl mmol/L39.7 - 40.3PassCa mmol/L1.97 - 2.03PassMg mmol/L1.48 - 1.52Pass	Spec         Pass/Fail           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 23181020	Flush L/N 23187064	Reference L/N 23180067
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	Aqueous Salt N/A Present Solution	Spec Pass/Fail 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

Amishi.M

Approval

QC Inspector

Title

9/11/2023

Date