

## **CERTIFICATE OF ANALYSIS**

STP pHOx Ultra/CCX Cal Cartridge 1 w/Creat Lot Number 24072019

Ref Number 48836 Exp Date 2025-08-16

Date of Manufacture 2024-02-16

UDI# (01)00385480488365(11)240216(17)250816(10)24072019

Cal A L/N 24047073		Cal B L/N	24047074		Cal C L/N	24047075	
Spec pH @ 37C 7.351 - 7.357 Lac mmol/L 13.5 - 16.5	Pass/Fail Pass Pass	pH @ 37C Na mmol/L K mmol/L CI mmol/L Ca mmol/L Mg mmol/L	<u>Spec</u> 6.822 - 6.828 69.5 - 70.5 9.9 - 10.1 39.7 - 40.3 1.97 - 2.03 1.48 - 1.52	Pass/Fail Pass Pass Pass Pass Pass Pass Pass	Na mmol/L K mmol/L Cl mmol/L BUN mg/dl Glu mg/dl Lac mmol/L Ca mmol/L Mg mmol/L Creat mg/dl HCO3 mmol/L	Spec 139.0 - 141.0 3.97 - 4.03 118.0 - 120.0 9.9 - 10.1 78.8 - 81.2 1.8 - 2.2 0.99 - 1.02 0.49 - 0.51 0.98 - 1.02 18.34 - 19.08	Pass Pass Pass Pass Pass Pass Pass Pass
Cal D L/N 24047076		Flush L/N	24053059		Reference L/N	24047072	
BUN mg/dl 49.4 - 50.6 Glu mg/dl 197 - 203 Lac mmol/L 5.5 - 6.5 Creat mg/dl 9.8 - 10.2 ICO3 mmol/L 36.68 - 38.18	Pass/Fail Pass Pass Pass Pass Pass Pass	Aqueous Salt Solution		Result Present	KCI mol/L	<u>Spec</u> 1.8 - 2.2	Pass/Fail 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

Haneen Aldarwish

Approval

QC Inspector

Title

3/20/2024

Date