

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Cal Cartridge 1 w/Creat Lot Number 24192049

1 w/Creat Ref Number 48836 Exp Date 2025-12-05 Date of Manufacture 2024-06-05 UDI# (01)00385480488365(11)240605(17)251205(10)24192049

Cal A L/N 24179034	Cal B L/N 24178013	Cal C L/N 24178014
<u>Spec</u> <u>Pass/Fail</u> pH @ 37C 7.351 - 7.357 Pass Lac mmol/L 13.5 - 16.5 Pass	Spec Pass/Fail pH @ 37C 6.822 - 6.828 Pass Na mmol/L 69.5 - 70.5 Pass K mmol/L 9.9 - 10.1 Pass CI 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 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 Mg 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 24178015	Flush L/N 24183032	Reference L/N 24180022
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

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Approval

QC Inspector Title

<u>7/15/2024</u> Date