

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Chemistry Controls Auto-Cartridge 4/Day Lot Number 24138012

ols Ref Number 48906 Exp Date 2025-11-07 Date of Manufacture 2024-05-07 UDI# (01)00385480489065(11)240507(17)251107(10)24138012

	Level 4				Level 5	
	<u>Spec</u>	Pass/Fail			Spec	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	0.55 - 0.63	Pass		Mg++ mmol/L	1.04 - 1.16	Pass
Glu mg/dL	78 - 82	Pass		Glu mg/dL	274 - 286	Pass
Lac mmol/L	1.9 - 2.1	Pass		Lac mmol/L	7.3 - 7.5	Pass
BUN mg/dL	18.5 - 19.5	Pass		BUN mg/dL	54.6 - 57.4	Pass
			Level 6			
		0				
		Q	C Performance Check			
			Spec	Pass/Fail		

Spec Pass/Fail Glu mg/dL 700 - 1500 Pass

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

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Approval

QC Inspector Title

<u>5/31/2024</u> Date