

CERTIFICATE OF ANALYSIS

STP pHOX Ultra/CCX Chemistry Controls & Performance Check Auto-Cartridge Lot Number 23243055

trols & Ref Number 48906 ge Exp Date 2025-02-21 Date of Manufacture 2023-08-21 UDI# (01)00385480489065(11)230821(17)250221(10)23243055

Level 4				Level 5	
<u>Spec</u>	Pass/Fail			<u>Spec</u>	Pass/Fail
141.8 - 144.6	Pass		Na+ mmol/L	115.6 - 118.0	Pass
4.01 - 4.09	Pass		K+ mmol/L	6.51 - 6.65	Pass
125.4 - 128.0	Pass		CI- mmol/L	95.0 - 97.0	Pass
1.10 - 1.12	Pass		Ca++ mmol/L	1.60 - 1.64	Pass
0.59 - 0.67	Pass		Mg++ mmol/L	1.01 - 1.13	Pass
78 - 82	Pass		Glu mg/dL	274 - 286	Pass
1.9 - 2.1	Pass		Lac mmol/L	7.2 - 7.4	Pass
18.5 - 19.5	Pass		BUN mg/dL	54.6 - 57.4	Pass
		l evel 6			
			Pass/Fail		
	Glu ma/dl				
	<u>Spec</u> 141.8 - 144.6 4.01 - 4.09 125.4 - 128.0 1.10 - 1.12 0.59 - 0.67 78 - 82 1.9 - 2.1	SpecPass/Fail141.8 - 144.6Pass4.01 - 4.09Pass125.4 - 128.0Pass1.10 - 1.12Pass0.59 - 0.67Pass78 - 82Pass1.9 - 2.1Pass18.5 - 19.5Pass	Spec Pass/Fail 141.8 - 144.6 Pass 4.01 - 4.09 Pass 125.4 - 128.0 Pass 1.10 - 1.12 Pass 0.59 - 0.67 Pass 78 - 82 Pass 1.9 - 2.1 Pass 18.5 - 19.5 Pass	Spec Pass/Fail 141.8 - 144.6 Pass Na+ mmol/L 4.01 - 4.09 Pass K+ mmol/L 125.4 - 128.0 Pass Cl- mmol/L 1.10 - 1.12 Pass Ca++ mmol/L 0.59 - 0.67 Pass Mg++ mmol/L 78 - 82 Pass Glu mg/dL 1.9 - 2.1 Pass Lac mmol/L 18.5 - 19.5 Pass BUN mg/dL	Spec Pass/Fail Spec 141.8 - 144.6 Pass Na+ mmol/L 115.6 - 118.0 4.01 - 4.09 Pass K+ mmol/L 6.51 - 6.65 125.4 - 128.0 Pass CI- mmol/L 95.0 - 97.0 1.10 - 1.12 Pass Ca++ mmol/L 1.60 - 1.64 0.59 - 0.67 Pass Mg++ mmol/L 1.01 - 1.13 78 - 82 Pass Glu mg/dL 274 - 286 1.9 - 2.1 Pass Lac mmol/L 7.2 - 7.4 18.5 - 19.5 Pass BUN mg/dL 54.6 - 57.4

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

<u>10/11/2023</u> Date