

## **CERTIFICATE OF ANALYSIS**

STP pHOx Plus L Controls Auto-Cartridge Lot Number 24212072

rtridge Ref Number 34091 Exp Date 2025-12-12 Date of Manufacture 2024-06-12 UDI#(01)00385480340915(11)240612(17)251212(10)24212072

	Level 1				Level 2	
	<u>Spec</u>	Pass/Fail			<u>Spec</u>	Pass/Fail
pН	7.140 - 7.215	Pass		рH	7.345 - 7.395	Pass
pCO2 mmHg	55.0 - 60.0	Pass		pCO2 mmHg	38.0 - 44.0	Pass
pO2 mmHg	53.0 - 63.0	Pass		pO2 mmHg	104.0 - 116.0	Pass
Na+ mmol/L	158.0 - 163.0	Pass		SO2 %	58.0 - 64.0	Pass
K+ mmol/L	5.65 - 5.95	Pass		Hct %	33 - 37	Pass
CI- mmol/L	119.5 - 128.5	Pass		Na+ mmol/L	136.0 - 140.0	Pass
Ca++ mmol/L	1.36 - 1.44	Pass		K+ mmol/L	3.80 - 4.00	Pass
Glu mg/dL	270 - 320	Pass		CI- mmol/L	96.0 - 104.0	Pass
Lac mmol/L	6.4 - 7.7	Pass		Ca++ mmol/L	0.91 - 0.99	Pass
				Glu mg/dL	184 - 214	Pass
				Lac mmol/L	2.6 - 3.2	Pass
			Level 3			
				Daga/Eail		
			 Spec	<u>Pass/Fail</u>		

	Spec	Pass/Fai
pН	7.575 - 7.615	Pass
pCO2 mmHg	19.8 - 24.8	Pass
pO2 mmHg	130.0 - 150.0	Pass
SO2 %	85.0 - 93.0	Pass
Hct %	49 - 53	Pass
Na+ mmol/L	113.0 - 118.0	Pass
K+ mmol/L	1.85 - 2.15	Pass
CI- mmol/L	80.0 - 88.0	Pass
Ca++ mmol/L	0.53 - 0.63	Pass
Glu mg/dL	77 - 91	Pass
Lac mmol/L	0.9 - 1.3	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. SO2 is traced to tonometry.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Haneen Aldarwish

Approval

<u>QC Inspector</u> Title

<u>9/6/2024</u> Date