

## **CERTIFICATE OF ANALYSIS**

STP pHOx Plus/Plus C Controls Auto-Cartridge Lot Number 24124029

o-Cartridge Ref Number 30646 Exp Date 2025-10-23 Date of Manufacture 2024-04-23 UDI# (01)00385480306461(11)240423(17)251023(10)24124029

	Level 1				Level 2	
	<u>Spec</u>	Pass/Fail			<u>Spec</u>	Pass/Fail
pН	7.140 - 7.215	Pass		pН	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	155.5 - 160.5	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	1.30 - 1.40	Pass		K+ mmol/L	3.80 - 4.00	Pass
Glu mg/dL	270 - 320	Pass		CI- mmol/L	96.0 - 104.0	Pass
				Ca++ mmol/L	0.91 - 0.99	Pass
				Glu mg/dL	184 - 214	Pass
		Level 3				
		Spec	Pass/Fail			
	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	115.0 - 120.0	Pass			
	K+ mmol/L	1.90 - 2.20	Pass			
	CI- mmol/L	81.0 - 89.0	Pass			
	Ca++ mmol/L	0.53 - 0.63	Pass			
	Glu mg/dL	77 - 91	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

Approval

QC Inspector Title

<u>5/29/2024</u> Date