

## **CERTIFICATE OF ANALYSIS**

STP pHOx Plus L Controls Auto-Cartridge Lot Number 23240011

Ref Number 34090 Exp Date 2025-02-03 Date of manufacture 2023-08-03

UDI# (01)00385480340908(11)230803(17)250203(10)23240011

Level 1				Level 2		
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail	
рН	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	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	
	<u>Spec</u>	Pass/Fail
рН	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

QC Inspector

Title

10/4/2023

Date