

CERTIFICATE OF ANALYSIS

STP pHOx Plus L Controls Auto-Cartridge Lot Number 22033058

D-Cartridge Ref Number 34090 Exp Date 2023-07-18 Date of manufacture 2022-01-18

UDI# (01)00385480340908(11)220118(17)230718(10)22033058

	Level 1			Level 2	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
pН	7.140 - 7.215	Pass	pH	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					
		<u>S</u>	pec <u>F</u>	<u>Pass/Fail</u>	
	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

Approval

QC Inspector Title

<u>2/22/2022</u> Date