

## **CERTIFICATE OF ANALYSIS**

STP pHOx Plus L Control Levels 1, 2, 3 - Ampules Lot Number 23128037

Ref Nu	Ref Number 34117		
Exp Date	2025-04-12		
Date of Manufacture	2023-04-12		

Level	1 L/N: 2310202	27	Leve	el 2 L/N:	231020	29
Level 1 Exp	Date: 2025-04	-12	Level 2 Ex	vp Date:	2025-04	4-12
	<u>Spec</u>	Pass/Fail		<u>S</u>	pec	Pass/Fail
pН	7.165 - 7.205	Pass	pH	7.380	- 7.420	Pass
pCO2 mmHg	57.0 -67.0	Pass	pCO2 mmHg	37.0	- 43.0	Pass
pO2 mmHg	53.0 - 63.0	Pass	pO2 mmHg	93.0	- 103.0	Pass
Na+ mmol/L	158.0 - 162.0	Pass	SO2 %	58.0	- 64.0	Pass
K+ mmol/L	5.35 - 5.65	Pass	Hct %	33	- 37	Pass
CI- mmol/L	118.0 - 127.0	Pass	Na+ mmol/L	134.0	- 138.0	Pass
Ca++ mmol/L	1.36 - 1.44	Pass	K+ mmol/L	3.75	- 3.95	Pass
Glu mg/dL	260 - 310	Pass	CI- mmol/L	95.0	- 103.0	Pass
Lac mmol/L	6.4 - 7.7	Pass	Ca++ mmol/L	0.90	- 0.98	Pass
			Glu mg/dL	184	- 214	Pass
			Lac mmol/L	2.6	- 3.2	Pass

## Level 3 L/N: 23103058 Level 3 Exp Date: 2025-04-13

Level 3 LAP Date. 2023-04-13				
	<u>Spec</u>	Pass/Fail		
pН	7.590 - 7.630	Pass		
pCO2 mmHg	17.5 - 22.5	Pass		
pO2 mmHg	131.0 - 145.0	Pass		
SO2 %	88.0 - 96.0	Pass		
Hct %	48 - 52	Pass		
Na+ mmol/L	113.0 - 118.0	Pass		
K+ mmol/L	2.00 - 2.30	Pass		
CI- mmol/L	84.0 - 92.0	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 manufacture

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Approval

QC Inspector Title

<u>3/12/2024</u> Date