

CERTIFICATE OF ANALYSIS

STP pHOx Plus L Control Levels 1, 2, 3 - Ampules Lot Number 24135029

Ref Nu	Ref Number 34117			
Exp Date	2026-05-09			
Date of Manufacture	2024-05-09			

Level	1 L/N: 241300	13	Leve	el 2 L/N:	241300	14
Level 1 Exp	Date: 2026-05	-09	Level 2 Ex	vp Date:	2026-05	5-09
	<u>Spec</u>	Pass/Fail		<u>Sr</u>	<u>bec</u>	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: 24130015 Level 3 Exp Date: 2026-05-09

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	<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

State

Approval

QC Inspector Title

<u>06/18/2024</u> Date