

CERTIFICATE OF ANALYSIS

STP pHOx Plus/Plus C Controls Auto-Cartridge Lot Number 23311060 Ref Number 30646 Exp Date 2025-04-20

Date of Manufacture 2023-10-20

UDI# (01)00385480306461(11)231020(17)250420(10)23311060

	Level 1			Level 2	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
рН	7.140 - 7.215	Pass	рН	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					
	<u>Spec</u>	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			

Laval 2

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

12/6/2023

Date