



CERTIFICATE OF ANALYSIS

STP pHox Plus/Plus C Controls Auto-Cartridge
Lot Number 24058041

Ref Number 30643
Exp Date 2025-08-02
Date of Manufacture 2024-02-02
UDI# (01)00385480306430(11)240202(17)250802(10)24058041

Level 1			Level 2		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
pH	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	155.5 - 160.5	Pass	SO2 %	58.0 - 64.0	Pass
K+ mmol/L	5.65 - 5.95	Pass	Hct %	33 - 37	Pass
Cl- 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	Cl- 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>	<u>Pass/Fail</u>
pH	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
Cl- mmol/L	81.0 - 89.0	Pass
Ca++ mmol/L	0.53 - 0.63	Pass
Glu mg/dL	77 - 91	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

4/16/2024

Date