

NOVA
biomedical
CERTIFICATE OF ANALYSIS

STP pHox Plus L Controls Auto-Cartridge
Lot Number 22257050

Ref Number 34093
Exp Date 2024-02-26

Date of Manufacture 2022-08-26

UDI# (01)00385480340939(11)220826(17)240226(10)22257050

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	158.0 - 163.0	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	1.36 - 1.44	Pass	K+ mmol/L	3.80 - 4.00	Pass
Glu mg/dL	270 - 320	Pass	Cl- 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 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	113.0 - 118.0	Pass
K+ mmol/L	1.85 - 2.15	Pass
Cl- 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

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Approval

QC Inspector
Title

10/5/2022
Date