



**CERTIFICATE OF ANALYSIS**

STP pHox Plus M Controls Auto-Cartridge

Ref Number 45206

Lot Number 24180012

Exp Date 2025-12-24

Date of Manufacture 2024-06-24

UDI# (01)00385480452069(11)240624(17)251224(10)24180012

Level 1			Level 2		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
pH	7.110 - 7.190	Pass	pH	7.350 - 7.420	Pass
pCO2 mmHg	55.0 - 65.0	Pass	pCO2 mmHg	39.0 - 45.0	Pass
pO2 mmHg	58.0 - 68.0	Pass	pO2 mmHg	97.0 - 107.0	Pass
Na+ mmol/L	157.8 - 161.8	Pass	Hct %	35 - 39	Pass
K+ mmol/L	5.71 - 6.01	Pass	Na+ mmol/L	138.5 - 142.5	Pass
Mg++ mmol/L	0.83 - 0.97	Pass	K+ mmol/L	3.85 - 4.05	Pass
Ca++ mmol/L	1.43 - 1.51	Pass	Mg++ mmol/L	0.52 - 0.60	Pass
Glu mg/dL	73 - 87	Pass	Ca++ mmol/L	0.93 - 1.01	Pass
Lac mmol/L	0.6 - 1.0	Pass	Glu mg/dL	185 - 215	Pass
			Lac mmol/L	2.6 - 3.2	Pass

  

Level 3		
	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.570 - 7.650	Pass
pCO2 mmHg	18.0 - 26.0	Pass
pO2 mmHg	135.0 - 149.0	Pass
Hct %	47 - 51	Pass
Na+ mmol/L	117.5 - 121.5	Pass
K+ mmol/L	1.95 - 2.25	Pass
Mg++ mmol/L	0.28 - 0.36	Pass
Ca++ mmol/L	0.50 - 0.60	Pass
Glu mg/dL	275 - 325	Pass
Lac mmol/L	6.4 - 7.7	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.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manu

Approval

QC Inspector

Title

7/10/2024

Date