



CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Blood Gas Control
Auto-Cartridge
Lot Number 23271019

Ref Number 48904
Exp Date 2025-03-11
Date of Manufacture 2023-09-11
UDI# (01)00385480489041(11)230911(17)250311(10)23271019

Level 1			Level 2		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
pH	7.179 - 7.254	Pass	pH	7.410 - 7.460	Pass
PCO2 mmHg	55.0 - 60.0	Pass	PCO2 mmHg	39.8 - 45.8	Pass
PO2 mmHg	53.0 - 63.0	Pass	PO2 mmHg	104.0 - 116.0	Pass
SO2 %	55.0 - 61.0	Pass			
Hct %	32 - 36	Pass			

Level 3		
	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.555 - 7.630	Pass
PCO2 mmHg	21.5 - 26.5	Pass
PO2 mmHg	130.0 - 150.0	Pass
SO2 %	90.0 - 96.0	Pass
Hct %	48 - 52	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

10/20/2023
Date