

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Blood Gas Control

Ref Number 48904

Auto-Cartridge

Exp Date 2025-11-02

Lot Number 24134043

Date of Manufacture 2024-05-02

UDI# (01)00385480489041(11)240502(17)251102(10)24134043

Level 1				Level 2		
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail	
pH 7	7.179 - 7.254	Pass	рН	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>	Pass/Fail
рН	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

Approval

QC Inspector

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Title

6/11/2024

Date