

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Blood Gas Control Auto-Cartridge Lot Number 24226037

trol Ref Number 48903 Exp Date 2026-01-25 Date of Manufacture 2024-07-25 UDI# (01)00385480489034(11)240725(17)260125(10)24226037

	Level 1			Level 2	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
pН	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
7.555 - 7.630	Pass
21.5 - 26.5	Pass
130.0 - 150.0	Pass
90.0 - 96.0	Pass
48 - 52	Pass
	<u>Spec</u> 7.555 - 7.630 21.5 - 26.5 130.0 - 150.0 90.0 - 96.0

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

<u>QC Inspector</u> Title

<u>9/4/2024</u> Date