

## **CERTIFICATE OF ANALYSIS**

STP pHOx Ultra/CCX Blood Gas Control Auto-Cartridge Lot Number 24134043

trol Ref Number 48903 Exp Date 2025-11-02 Date of Manufacture 2024-05-02 UDI# (01)00385480489034(11)240502(17)251102(10)24134043

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

	Level 3	
	<u>Spec</u>	Pass/Fail
pН	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

Auishi.M

Approval

QC Inspector Title

6/13/2024 Date