

CERTIFICATE OF ANALYSIS

STP pHOx Ultra/CCX Blood Gas Control

32 - 36

Pass

Ref Number 48904

Auto-Cartridge

Exp Date 2025-09-07

Lot Number 24087012

Hct %

Date of Manufacture 2024-03-07 UDI# (01)00385480489041(11)240307(17)250907(10)24087012

Level 1 Level 2 **Spec** Pass/Fail **Spec** Pass/Fail pH 7.179 - 7.254 7.410 - 7.460 Pass Pass рΗ PCO2 mmHg 55.0 - 60.0 Pass PCO₂ mmH_q 39.8 - 45.8 Pass PO2 mmHg 53.0 - 63.0 PO2 mmHg 104.0 - 116.0 Pass Pass 55.0 - 61.0 SO2 % 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

Title

4/9/2024 Date