



## CERTIFICATE OF ANALYSIS

STP pHox Ultra/CCX Blood Gas Control

Ref Number 48904

Auto-Cartridge

Exp Date 2026-07-28

Lot Number 25034072

Date of Manufacture 2025-01-28

UDI# (01)00385480489041(11)250128(17)260728(10)25034072

| 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

2/13/2025

Date