

CERTIFICATE OF ANALYSIS

STP pHOxUltra Controls Lot Number 25055037 Ref Number 48935 Exp Date 2027-02-18 Date of Manufacture 2025-02-18 UDI# (01)00385480489355(11)250218(17)270218(10)25055037

Level 1 L/N: 25049007 Level 2 L/N: 25049008 Level 1 Exp Date: 2027-02-18 Level 2 Exp Date: 2027-02-18

	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
рН	7.180 - 7.220	Pass	рН	7.395 - 7.435	Pass
PCO2 mmHg	55.0 - 65.0	Pass	PCO2 mmHg	40.0 - 46.0	Pass
PO2 mmHg	55.0 - 65.0	Pass	PO2 mmHg	93.0 - 103.0	Pass
SO2 %	59.0 - 65.0	Pass			
Hct %	32 - 36	Pass			

Level 3 L/N: 25049009 Level 3 Exp Date: 2027-02-18

	<u>Spec</u>	Pass/Fail	
рН	7.545 - 7.585	Pass	
PCO2 mmHg	22.0 - 27.0	Pass	
PO2 mmHg	131.0 - 145.0	Pass	
SO2 %	89.0 - 97.0	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

4/8/2025 Date