

CERTIFICATE OF ANALYSIS

STP pHOxUltra Controls Lot Number 24213029

Ref Number 48935 Exp Date 2026-07-26 Date of Manufacture 2024-07-26 UDI# (01)00385480489355(11)240726(17)260726(10)24213029

Level 1 L/N: 24208078 Level 1 Exp Date: 2026-07-26 Level 2 L/N: 24212074

Level 2 Exp Date: 2026-07-30

	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
pН	7.180 - 7.220	Pass	pH	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: 24215017

Level 3 Exp Date: 2026-08-02

<u>Pass/Fail</u>	
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

<u>9/5/2024</u> Date