



CERTIFICATE OF ANALYSIS

STP pHoxUltra Controls
Lot Number 23160034

Ref Number 48935
Exp Date 2025-05-30
Date of Manufacture 2023-05-30
UDI# (01)00385480489355(11)230530(17)250530(10)23160034

Level 1 L/N: 23150039
Level 1 Exp Date: 2025-05-30

Level 2 L/N: 23156060
Level 2 Exp Date: 2025-06-05

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.180 - 7.220	Pass
PCO2 mmHg	55.0 - 65.0	Pass
PO2 mmHg	55.0 - 65.0	Pass
SO2 %	59.0 - 65.0	Pass
Hct %	32 - 36	Pass

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.395 - 7.435	Pass
PCO2 mmHg	40.0 - 46.0	Pass
PO2 mmHg	93.0 - 103.0	Pass

Level 3 L/N: 23150041
Level 3 Exp Date: 2025-05-30

	<u>Spec</u>	<u>Pass/Fail</u>
pH	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

Haneen Aldarwish

Approval

QC Inspector
Title

7/11/2023
Date