



CERTIFICATE OF ANALYSIS

STP pHox/Basic Controls Auto-Cartridge

Lot Number 25065018

Ref Number 23933

Exp Date 2026-08-26

Date of Manufacture 2025-02-26

UDI# (01)00385480239332(11)250226(17)260826(10)25065018

Level 1			Level 2		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
pH	7.229-7.304	Pass	pH	7.405-7.455	Pass
pCO2 mmHg	55.0-60.0	Pass	pCO2 mmHg	38.0-44.0	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	7.543-7.593	Pass
pCO2 mmHg	21.0-26.0	Pass
pO2 mmHg	130.0-150.0	Pass
SO2 %	84.0-90.0	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