

CERTIFICATE OF ANALYSIS

BioProfile pHOx Auto-Cartridge QC Lot Number 23199011 Ref Number 42751 Exp Date 2024-12

	Level 1			Level 2	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
рН	6.600 - 6.800	Pass	рН	6.750 - 6.950	Pass
PCO2 mmHg	57.0 - 67.0	Pass	PCO2 mmHg	37.0 - 43.0	Pass
PO2 mmHg	53.0 - 63.0	Pass	PO2 mmHg	93.0 - 103.0	Pass

Level 3

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

pH 7.200 - 7.400 Pass

PCO2 mmHg 17.5 - 22.5 Pass

PO2 mmHg 133.0 - 143.0 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. The following analytes are traceable

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector Title

Haneen Aldarwish

8/1/2023

Date