



CERTIFICATE OF ANALYSIS

Bioprofile FLEX 2 pH/Gas Auto QC Cartridge
Lot Number 25094031

Ref Number 56073
Exp Date 2026-09-30
Date of Manufacture 2025-03-31

	Level 1		Level 2	
	<u>Spec</u>	<u>Result</u>	<u>Spec</u>	<u>Result</u>
pH	6.600 - 6.800	Pass	pH 7.200 - 7.400	Pass
pO2 mmHg	53.0 - 63.0	Pass	pO2 mmHg 133.0 - 143.0	Pass
pCO2 mmHg	57.0 - 67.0	Pass	pCO2 mmHg 17.5 - 22.5	Pass
Osmolality, mOsm / kgH2O	195 - 205	Pass	Osmolality, mOsm / kgH2O 597 - 613	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 to NIST SRM Materials: pH.

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

Haneen Aldarwish

Approval

QC Inspector
Title

5/22/2025
Date