



CERTIFICATE OF ANALYSIS

Bioprofile FLEX 2 pH/Gas Auto QC Cartridge
Lot Number 25353054

Ref Number 56073
Exp Date 2027-06-12
Date of Manufacture 2025-12-12

| 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

Approval

QC Inspector
Title

2/13/2026
Date