

CERTIFICATE OF ANALYSIS

BioProfile pHOx Auto-Cartridge QC Lot Number 23348052 Ref Number 42751 Exp Date 2025-07

| | 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> | Pass/Fail |
| рН | 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

Auishi. M Approval

QC Inspector Title

1/29/2024 Date