



CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 100 Sample
Lot Number 24081027

Ref Number 53456

Exp Date 2025-09-07

Date of Manufacture 2024-03-07

UDI# (01)00385480534567(11)240307(17)250907(10)24081027

| Level 1 | | | Level 2 | | |
|----------------|---------------|------------------|----------------|---------------|------------------|
| | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| pH | 7.110 - 7.190 | Pass | pH | 7.350 - 7.420 | Pass |
| pCO2 mmHg | 55.0 - 65.0 | Pass | pCO2 mmHg | 39.0 - 45.0 | Pass |
| pO2 mmHg | 58.0 - 68.0 | Pass | pO2 mmHg | 97.0 - 107.0 | Pass |

| Level 3 | | |
|----------------|---------------|------------------|
| | <u>Spec</u> | <u>Pass/Fail</u> |
| pH | 7.570 - 7.650 | Pass |
| pCO2 mmHg | 18.0 - 26.0 | Pass |
| pO2 mmHg | 135.0 - 149.0 | 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. All listed analytes are traceable to NIST SRM Materials.

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

Approval

QC Inspector
Title

4/1/2024
Date