

CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 100 Sample Lot Number 23332052 Ref Number 53456 Exp Date 2025-05-13

Date of Manufacture 2023-11-13

UDI# (01)00385480534567(11)231113(17)250513(10)23332052

	Level 1			Level 2	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
pН	7.110 - 7.190	Pass	рН	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 Spec Pass/Fail 7.570 - 7.650 Pass

pCO2 mmHg 18.0 - 26.0 Pass pO2 mmHg 135.0 - 149.0 Pass

рΗ

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

E mi

12/13/2023 Date