

CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 100 Sample Lot Number 24123051 Ref Number 53456 Exp Date 2025-10-24 Date of Manufacture 2024-04-24

UDI# (01)00385480534567(11)240424(17)251024(10)24123051

	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

	<u>Spec</u>	Pass/Fail
рН	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

5/23/2024

Date