

CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 200 Sample Ref Number 53107 Lot Number 25086034 Exp Date 2026-09-17 Date of Manufacture 2025-03-17 UDI# (01)00385480531078(11)250317(17)260917(10)25086034

Level 1 Level 2 Spec Pass/Fail Spec Pass/Fail pН 7.110 - 7.190 Pass pН 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
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

mar.

Approval

QC Inspector Title

<u>4/28/2025</u> Date