



CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 300 Sample
Lot Number 25199061

Ref Number 53108

Exp Date 2026-12-30

Date of Manufacture 2025-06-30

UDI# (01)00385480531085(11)250630(17)261230(10)25199061

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

08/29/2025
Date