



**CERTIFICATE OF ANALYSIS**

Prime Auto QC Cartridge ABG 200 Sample  
Lot Number 23332052

Ref Number 53107

Exp Date 2025-05-13

Date of Manufacture 2023-11-13

UDI# (01)00385480531078(11)231113(17)250513(10)23332052

<b>Level 1</b>			<b>Level 2</b>		
	<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

  

<b>Level 3</b>		
	<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

*Haneen Aldarwish*

Approval

QC Inspector  
Title

12/15/2023  
Date