



CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 300 Sample
Lot Number 24233055

Ref Number 53108

Exp Date 2026-02-08

Date of Manufacture 2024-08-08

UDI# (01)00385480531085(11)240808(17)260208(10)24233055

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>		<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

09/04/2024
Date