nova biomedical

CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge ABG 100 Sample
Lot Number 25101039

Ref Number 53456
Exp Date 2026-10-01
Date of Manufacture 2025-04-01
UDI# (01)00385480534567(11)250401(17)261001(10)25101039

Level 1

	Spec	Pass/Fail
pH	7.110 - 7.190	Pass
pCO2 mmHg	55.0 - 65.0	Pass
pO2 mmHg	58.0 - 68.0	Pass

Level 2

	Spec	Pass/Fail
pH	7.350 - 7.420	Pass
pCO2 mmHg	39.0 - 45.0	Pass
pO2 mmHg	97.0 - 107.0	Pass

Level 3

	Spec	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

Haneen Aldarwish

Approval

QC Inspector
Title

5/16/2025
Date