nova biomedical

CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge CCS 200 Sample
Lot Number 25251012

Ref Number 45150
Exp Date 2027-02-28
Date of Manufacture 2025-08-28
UDI# (01)00385480451505(11)250828(17)270228(10)25251012

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
Na+ mmol/L	159.1 - 163.1	Pass
K+ mmol/L	5.71 - 6.01	Pass
Cl- mmol/L	126.8 - 135.8	Pass
Ca++ mmol/L	1.50 - 1.58	Pass
Glu mg/dL	72 - 86	Pass
Lac mmol/L	0.8 - 1.2	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
Na+ mmol/L	137.0 - 141.0	Pass
K+ mmol/L	3.76 - 3.96	Pass
Cl- mmol/L	96.5 - 104.5	Pass
Ca++ mmol/L	0.95 - 1.03	Pass
Glu mg/dL	182 - 212	Pass
Lac mmol/L	2.5 - 3.1	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
Na+ mmol/L	117.5 - 121.5	Pass
K+ mmol/L	1.80 - 2.10	Pass
Cl- mmol/L	81.2 - 89.2	Pass
Ca++ mmol/L	0.51 - 0.61	Pass
Glu mg/dL	292 - 330	Pass
Lac mmol/L	6.4 - 7.7	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

09/24/2025
Date