



CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge CCS 100 Sample
Lot Number 24071077

Ref Number 53455
Exp Date 2025-08-29

Date of Manufacture 2024-02-29

UDI# (01)00385480534550(11)240229(17)250829(10)24071077

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
Na+ mmol/L	159.1 - 163.1	Pass	Na+ mmol/L	137.0 - 141.0	Pass
K+ mmol/L	5.71 - 6.01	Pass	K+ mmol/L	3.76 - 3.96	Pass
Cl- mmol/L	126.8 - 135.8	Pass	Cl- mmol/L	96.5 - 104.5	Pass
Ca++ mmol/L	1.50 - 1.58	Pass	Ca++ mmol/L	0.95 - 1.03	Pass
Glu mg/dL	72 - 86	Pass	Glu mg/dL	182 - 212	Pass
Lac mmol/L	0.8 - 1.2	Pass	Lac mmol/L	2.5 - 3.1	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
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

Haneen Aldarwish

Approval

QC Inspector

Title

03/18/2024

Date