



CERTIFICATE OF ANALYSIS

Prime Auto QC Cartridge CCS 100 Sample
Lot Number 23332052

Ref Number 53455

Exp Date 2025-05-13

Date of Manufacture 2023-11-13

UDI# (01)00385480534550(11)231113(17)250513(10)23332052

| 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

12/18/2023

Date