



**CERTIFICATE OF ANALYSIS**

STP Prime Controls Auto QC Cartridge CCS  
Lot Number 21321046

Ref Number 45150  
Exp Date 2023-04-30  
Date of Manufacture 2021-10-30  
UDI# (01)00385480451505(11)211030(17)230430(10)21321046

| Level 1     |               |                  |
|-------------|---------------|------------------|
|             | <u>Spec</u>   | <u>Pass/Fail</u> |
| 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     |               |                  |
|-------------|---------------|------------------|
|             | <u>Spec</u>   | <u>Pass/Fail</u> |
| 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     |               |                  |
|-------------|---------------|------------------|
|             | <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

Approval

QC Inspector

Title

12/14/2021

Date