



### CERTIFICATE OF ANALYSIS

STP Prime Controls Auto QC Cartridge CCS  
Lot Number 16117016

Ref Number 53455  
Exp Date 2017-10-01  
Date of Manufacture 2016-04-01

| 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  | 151.7-161.7 | Pass      |
| K+ mmol/L   | 5.71-6.01   | Pass      |
| Cl- mmol/L  | 126.8-135.8 | Pass      |
| Ca++ mmol/L | 1.55-1.63   | Pass      |
| Glu mg/dL   | 66-82       | Pass      |
| Lac mmol/L  | 0.6-1.0     | 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      |
| Na+ mmol/L  | 136.2-140.2 | Pass      |
| K+ mmol/L   | 3.76-3.96   | Pass      |
| Cl- mmol/L  | 97.9-105.9  | Pass      |
| Ca++ mmol/L | 0.98-1.06   | Pass      |
| Glu mg/dL   | 176-206     | 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  | 116.6-120.6 | Pass      |
| K+ mmol/L   | 1.75-2.05   | Pass      |
| Cl- mmol/L  | 81.2-89.2   | Pass      |
| Ca++ mmol/L | 0.51-0.61   | Pass      |
| Glu mg/dL   | 275-325     | 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 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

  
Approval

QC Supervisor  
Title

5/9/2016  
Date