



CERTIFICATE OF ANALYSIS

STP Prime+ Cal-Cartridge 500 Sample w. Creat/BUN
Lot Number 25030034

Ref Number 57835

Exp Date 2026-07-21

Date of Manufacture 2025-01-21

UDI# (01)00385480578356(11)250121(17)260721(10)25030034

| Cal A | L/N | 25021032 | Cal B | L/N | 25021033 | Cal C | L/N | 25021034 | |
|-------------|-----|---------------|------------------|-----------|------------------------|------------------|-------------|---------------|------------------|
| | | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| HCO3 mmol/L | | 10.78 - 11.22 | Pass | pH | 6.831 - 6.837 | Pass | HCO3 mmol/L | 21.56 - 22.44 | Pass |
| Na mmol/L | | 134.6 - 136.4 | Pass | Na mmol/L | 76.5 - 77.5 | Pass | Cl mmol/L | 68.4 - 69.6 | Pass |
| K mmol/L | | 3.97 - 4.03 | Pass | K mmol/L | 9.92 - 10.08 | Pass | Glu mg/dL | 197 - 203 | Pass |
| Cl mmol/L | | 107.1 - 108.9 | Pass | Ca mmol/L | 1.89 - 1.95 | Pass | Lac mmol/L | 9.0 - 11.0 | Pass |
| Ca mmol/L | | 1.02 - 1.06 | Pass | Mg mmol/L | 1.48 - 1.52 | Pass | BUN mg/dL | 49.4 - 50.6 | Pass |
| Mg mmol/L | | 0.49 - 0.51 | Pass | | | | Creat mg/dL | 4.9 - 5.1 | Pass |
| Glu mg/dL | | 78.8 - 81.2 | Pass | | | | | | |
| Lac mmol/L | | 1.8 - 2.2 | Pass | | | | | | |
| BUN mg/dL | | 9.75 - 10.25 | Pass | | | | | | |
| Creat mg/dL | | 0.98 - 1.02 | Pass | | | | | | |
| | | | | | <u>Assigned Value*</u> | <u>Result</u> | | | |
| | | | | tHb g/dL | 15.4 | N/A | | | |

| Cal D | L/N | 25021035 | Flush | L/N | 25021030 | Reference | L/N | 25021020 | |
|----------|-----|---------------|------------------|-----|------------------------|---------------|-----|-------------|------------------|
| | | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Assigned Value*</u> | <u>Result</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| pH @ 37C | | 7.351 - 7.357 | Pass | PO2 | 103.0 | N/A | KCl | 1.8 - 2.2 | 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

Auishi M

Approval

QC Inspector

Title

2/7/2025

Date