

nova
biomedical
CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 105 Sample with Creat/BUN
Lot Number 25007025

Ref Number 57841
Exp Date 2026-06-20

Date of Manufacture 2024-12-20

UDI# (01)00385480578417(11)241220(17)260620(10)25007025

| Level 1 | | | Level 2 | | | Level 3 | | |
|------------------|---------------|------------------|------------------|---------------|------------------|------------|---------------|------------------|
| | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> |
| pH | 7.180 - 7.230 | Pass | pH | 7.350 - 7.420 | Pass | pH | 7.570 - 7.650 | Pass |
| pCO2 mmHg | 55.0 - 65.0 | Pass | pCO2 mmHg | 39.0 - 45.0 | Pass | pCO2 mmHg | 18.0 - 26.0 | Pass |
| pO2 mmHg | 58.0 - 68.0 | Pass | pO2 mmHg | 97.0 - 107.0 | Pass | pO2 mmHg | 135.0 - 149.0 | Pass |
| tHb g/dL | 18.0 - 22.0 | Pass | tHb g/dL | 13.0 - 16.0 | Pass | tHb g/dL | 5.5 - 8.5 | Pass |
| COHb % | 24.0 - 32.0 | Pass | COHb % | 17.0 - 23.0 | Pass | COHb % | 3.0 - 9.0 | Pass |
| tBil mg/dL | 18.0 - 24.0 | Pass | tBil mg/dL | 9.5 - 13.5 | Pass | tBil mg/dL | 4.0 - 8.0 | Pass |
| Level 4 | | | Level 5 | | | | | |
| | <u>Spec</u> | <u>Pass/Fail</u> | | <u>Spec</u> | <u>Pass/Fail</u> | | | |
| Na+ mmol/L | 141.9 - 144.7 | Pass | Na+ mmol/L | 114.0 - 116.4 | Pass | | | |
| K+ mmol/L | 3.94 - 4.02 | Pass | K+ mmol/L | 6.13 - 6.25 | Pass | | | |
| Cl- mmol/L | 126.6 - 129.2 | Pass | Cl- mmol/L | 96.9 - 98.9 | Pass | | | |
| Ca++ mmol/L | 1.07 - 1.09 | Pass | Ca++ mmol/L | 1.47 - 1.49 | Pass | | | |
| Glu mg/dL | 79 - 83 | Pass | Glu mg/dL | 265 - 275 | Pass | | | |
| BUN mg/dL | 17.6 - 18.5 | Pass | BUN mg/dL | 50.7 - 53.3 | Pass | | | |
| Creatinine mg/dL | 0.88 - 0.92 | Pass | Creatinine mg/dL | 6.47 - 6.73 | Pass | | | |
| Lac mmol/L | 1.7 - 2.3 | Pass | Lac mmol/L | 6.7 - 7.3 | Pass | | | |
| Mg++ mmol/L | 0.56 - 0.68 | Pass | Mg++ mmol/L | 1.14 - 1.26 | 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. tHb is traced by using Cyanmethoglobin method

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Haneen Aldarwish

Approval

QC Inspector
Title

01/30/2025
Date