

nova
biomedical
CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 315 Sample with Creat/BUN
Lot Number 25015043

Ref Number 57843
Exp Date 2026-07-08

Date of Manufacture 2025-01-08

UDI# (01)00385480578431(11)250108(17)260708(10)25015043

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	1.6 - 2.2	Pass	Lac mmol/L	6.6 - 7.2	Pass
Mg++ mmol/L	0.56 - 0.68	Pass	Mg++ mmol/L	1.16 - 1.28	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