

nova
biomedical
CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 320 Sample
Lot Number 24346048

Ref Number 57839
Exp Date 2026-06-02
Date of Manufacture 2024-12-02

UDI# (01)00385480578394(11)241202(17)260602(10)24346048

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			
Lac mmol/L	1.7 - 2.3	Pass	Lac mmol/L	6.7 - 7.3	Pass			
Mg++ mmol/L	0.54 - 0.66	Pass	Mg++ mmol/L	1.06 - 1.18	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

12/27/2024

Date