



CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 160 Sample
 Lot Number 25321028

Ref Number 57838
 Exp Date 2027-05-10
 Date of Manufacture 2025-11-10

UDI# (01)00385480578387(11)251110(17)270510(10)25321028

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>		<u>Spec</u>	<u>Pass/Fail</u>
Na+ mmol/L	139.3 - 142.1	Pass	Na+ mmol/L	113.9 - 116.3	Pass			
K+ mmol/L	3.90 - 3.98	Pass	K+ mmol/L	6.13 - 6.25	Pass			
Cl- mmol/L	125.2 - 127.8	Pass	Cl- mmol/L	97.5 - 99.5	Pass			
Ca++ mmol/L	1.06 - 1.08	Pass	Ca++ mmol/L	1.47 - 1.49	Pass			
Glu mg/dL	79 - 83	Pass	Glu mg/dL	279 - 291	Pass			
Lac mmol/L	1.7 - 2.3	Pass	Lac mmol/L	6.5 - 7.1	Pass			
Mg++ mmol/L	0.56 - 0.68	Pass	Mg++ mmol/L	1.03 - 1.15	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

Oliver Rammer

Approval

QC Inspector
 Title

12/10/2025
 Date