

nova
biomedical
CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 160 Sample
Lot Number 25169025

Ref Number 57838
Exp Date 2026-10-03
Date of Manufacture 2025-04-03

UDI# (01)00385480578387(11)250403(17)261003(10)25169025

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 <i>mmHg</i>	55.0 - 65.0	Pass	pCO2 <i>mmHg</i>	39.0 - 45.0	Pass	pCO2 <i>mmHg</i>	18.0 - 26.0	Pass
pO2 <i>mmHg</i>	58.0 - 68.0	Pass	pO2 <i>mmHg</i>	97.0 - 107.0	Pass	pO2 <i>mmHg</i>	135.0 - 149.0	Pass
tHb <i>g/dL</i>	18.0 - 22.0	Pass	tHb <i>g/dL</i>	13.0 - 16.0	Pass	tHb <i>g/dL</i>	5.5 - 8.5	Pass
COHb %	24.0 - 32.0	Pass	COHb %	17.0 - 23.0	Pass	COHb %	3.0 - 9.0	Pass
tBil <i>mg/dL</i>	18.0 - 24.0	Pass	tBil <i>mg/dL</i>	9.5 - 13.5	Pass	tBil <i>mg/dL</i>	4.0 - 8.0	Pass
Level 4			Level 5					
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>			
Na+ <i>mmol/L</i>	141.9 - 144.7	Pass	Na+ <i>mmol/L</i>	113.8 - 116.0	Pass			
K+ <i>mmol/L</i>	3.94 - 4.02	Pass	K+ <i>mmol/L</i>	6.14 - 6.26	Pass			
Cl- <i>mmol/L</i>	126.6 - 129.2	Pass	Cl- <i>mmol/L</i>	97.9 - 99.9	Pass			
Ca++ <i>mmol/L</i>	1.07 - 1.09	Pass	Ca++ <i>mmol/L</i>	1.44 - 1.46	Pass			
Glu <i>mg/dL</i>	79 - 83	Pass	Glu <i>mg/dL</i>	279 - 291	Pass			
Lac <i>mmol/L</i>	1.6 - 2.2	Pass	Lac <i>mmol/L</i>	6.5 - 7.1	Pass			
Mg++ <i>mmol/L</i>	0.52 - 0.64	Pass	Mg++ <i>mmol/L</i>	1.10 - 1.22	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



Approval

QC Inspector

Title

08/27/2025

Date