

## **CERTIFICATE OF ANALYSIS**

STP Prime Plus Calibrator Cartridge 400 Sample Lot Number 21340034 Ref Number 57828 Exp Date 2023-05-04 Date of Manufacture 2021-11-04 78288(11)211104(17)230504(10)21340034

UDI# (01)00385480578288(11)211104(17)230504(10)21340034

Cal A L/N	21317006		Cal B L/N	Cal B L/N 21317005	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
HCO3 mmol/L	10.78 - 11.22	Pass	pH	6.831 - 6.837	Pass
Na mmol/L	134.6 - 136.4	Pass	K mmol/L	9.92 - 10.08	Pass
K mmol/L	3.97 - 4.03	Pass	Ca mmol/L	1.89 - 1.95	Pass
CI mmol/L	107.1 - 108.9	Pass	Mg mmol/L	1.48 - 1.52	Pass
Ca mmol/L	1.02 - 1.06	Pass	Na mmol/L	76.5 - 77.5	Pass
Mg mmol/L	0.49 - 0.51	Pass			
Glu mg/dL	78.8 - 81.2	Pass		Assigned Value*	Result
Lac mmol/L	1.8 - 2.2	Pass	tHb g/dL	15.4	N/A
BUN mg/dL	9.75 - 10.25	Pass			
Cal C I/N	Cal C L/N 21322021		Cal D L/N	21322022	
	Spec	Pass/Fail		Spec	Pass/Fail
			pH @ 37C		
HCO3 mmol/L	21.56 - 22.44	Pass	pri @ 570	7.351 - 7.357	Pass
CI mmol/L	21.56 - 22.44 68.4 - 69.6	Pass Pass	pri @ 370	7.351 - 7.357	Pass
			pri e 370	7.351 - 7.357	Pass
CI mmol/L	68.4 - 69.6	Pass	pri e 370	7.351 - 7.357	Pass
CI mmol/L Glu mg/dL	68.4 - 69.6 197 - 203	Pass Pass	pri e 370	7.351 - 7.357	Pass
CI mmol/L Glu mg/dL Lac mmol/L BUN mg/dL	68.4 - 69.6 197 - 203 9.0 - 11.0 49.4 - 50.6	Pass Pass Pass			
CI mmol/L Glu mg/dL Lac mmol/L	68.4 - 69.6 197 - 203 9.0 - 11.0	Pass Pass Pass	Reference L/N		Pass 22025 Pass/Fail

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

\* NOTE: The "Assigned Values" are not to be considered specifications. They are used by the instrument for slope determination. The process of assigning these values at Nova Biomedical utilizes multiple sources of test data inputs as stipulated per the applicable procedures and therefore can result in changes from lot to lot.

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

Approval

QC Inspector Title

<u>12/17/2021</u> Date