

## **CERTIFICATE OF ANALYSIS**

STP Prime+ Cal-Cartridge 400 Sample w. Creat/BUN Lot Number 25030034

w. Creat/BUN Ref Number 57834 Exp Date 2026-07-21 Date of Manufacture 2025-01-21 UDI# (01)00385480578349(11)250121(17)260721(10)25030034

Cal A L/N	25021032		Cal B L/N	25021033		Cal C L/N	25021034	
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
HCO3 mmol/L	10.78 - 11.22	Pass	pН	6.831 - 6.837	Pass	HCO3 mmol/L	21.56 - 22.44	Pass
Na mmol/L	134.6 - 136.4	Pass	Na mmol/L	76.5 - 77.5	Pass	CI mmol/L	68.4 - 69.6	Pass
K mmol/L	3.97 - 4.03	Pass	K mmol/L	9.92 - 10.08	Pass	Glu mg/dL	197 - 203	Pass
Cl mmol/L	107.1 - 108.9	Pass	Ca mmol/L	1.89 - 1.95	Pass	Lac mmol/L	9.0 - 11.0	Pass
Ca mmol/L	1.02 - 1.06	Pass	Mg mmol/L	1.48 - 1.52	Pass	BUN mg/dL	49.4 - 50.6	Pass
Mg mmol/L	0.49 - 0.51	Pass				Creat mg/dL	4.9 - 5.1	Pass
Glu mg/dL	78.8 - 81.2	Pass						
Lac mmol/L	1.8 - 2.2	Pass	<u>As</u>	signed Value*	<u>Result</u>			
BUN mg/dL	9.75 - 10.25	Pass	tHb g/dL	15.4	N/A			
Creat mg/dL	0.98 - 1.02	Pass						
Cal D L/N 25021035		Flush L/N	Flush L/N 25021030		Reference L/N	25021020		
	<u>Spec</u>	Pass/Fail	<u>As</u>	<u>signed Value*</u>	<u>Result</u>		<u>Spec</u>	Pass/Fail
pH @ 37C	7.351 - 7.357	Pass	PO2	103.0	N/A	KCI	1.8 - 2.2	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.

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

Amishi.M

Approval

QC Inspector Title

<u>2/7/2025</u> Date