nova biomedical

CERTIFICATE OF ANALYSIS

STP Prime+ Cal-Cartridge 400 Sample w. Creat/BUN
Lot Number 25168091

Ref Number 57834
Exp Date 2026-11-30
Date of Manufacture 2025-05-30
UDI# (01)00385480578349(11)250530(17)261130(10)25168091

Cal A L/N 25156042

	Spec	Pass/Fail
HCO3 mmol/L	10.78 - 11.22	Pass
Na mmol/L	134.6 - 136.4	Pass
K mmol/L	3.97 - 4.03	Pass
Cl mmol/L	107.1 - 108.9	Pass
Ca mmol/L	1.02 - 1.06	Pass
Mg mmol/L	0.49 - 0.51	Pass
Glu mg/dL	78.8 - 81.2	Pass
Lac mmol/L	1.8 - 2.2	Pass
BUN mg/dL	9.75 - 10.25	Pass
Creat mg/dL	0.98 - 1.02	Pass

Cal B L/N 25156043

	Spec	Pass/Fail
pH	6.831 - 6.837	Pass
Na mmol/L	76.5 - 77.5	Pass
K mmol/L	9.92 - 10.08	Pass
Ca mmol/L	1.89 - 1.95	Pass
Mg mmol/L	1.48 - 1.52	Pass

	*Assigned Value**	*Result*
tHb g/dL	*15.5*	*N/A*

Cal C L/N 25156044

	Spec	Pass/Fail
HCO3 mmol/L	21.56 - 22.44	Pass
Cl mmol/L	68.4 - 69.6	Pass
Glu mg/dL	197 - 203	Pass
Lac mmol/L	9.0 - 11.0	Pass
BUN mg/dL	49.4 - 50.6	Pass
Creat mg/dL	4.9 - 5.1	Pass

Cal D L/N 25156045

	Spec	Pass/Fail
pH @ 37C	7.351 - 7.357	Pass

Flush L/N 25150046

	*Assigned Value**	*Result*
PO2	*101.0*	*N/A*

Reference L/N 25150045

	Spec	Pass/Fail
KCl	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

P. Hernandez
Approval

QC Inspector
Title

6/30/2025
Date