nova biomedical

CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 210 Sample with Creat/BUN
Lot Number 25211008

Ref Number 57842
Exp Date 2027-01-14
Date of Manufacture 2025-07-14
UDI# (01)00385480578424(11)250714(17)270114(10)25211008

Level 1

	Spec	Pass/Fail
pH	7.180 - 7.230	Pass
pCO2 *mmHg*	55.0 - 65.0	Pass
pO2 *mmHg*	58.0 - 68.0	Pass
tHb *g/dL*	18.0 - 22.0	Pass
COHb %	24.0 - 32.0	Pass
tBil *mg/dL*	18.0 - 24.0	Pass

Level 2

	Spec	Pass/Fail
pH	7.350 - 7.420	Pass
pCO2 *mmHg*	39.0 - 45.0	Pass
pO2 *mmHg*	97.0 - 107.0	Pass
tHb *g/dL*	13.0 - 16.0	Pass
COHb %	17.0 - 23.0	Pass
tBil *mg/dL*	9.5 - 13.5	Pass

Level 3

	Spec	Pass/Fail
pH	7.570 - 7.650	Pass
pCO2 *mmHg*	18.0 - 26.0	Pass
pO2 *mmHg*	135.0 - 149.0	Pass
tHb *g/dL*	5.5 - 8.5	Pass
COHb %	3.0 - 9.0	Pass
tBil *mg/dL*	4.0 - 8.0	Pass

Level 4

	Spec	Pass/Fail
Na+ *mmol/L*	140.6 - 143.4	Pass
K+ *mmol/L*	3.92 - 4.00	Pass
Cl- *mmol/L*	126.0 - 128.6	Pass
Ca++ *mmol/L*	1.07 - 1.09	Pass
Glu *mg/dL*	79 - 83	Pass
BUN *mg/dL*	15.6 - 16.4	Pass
Creatinine *mg/dL*	0.88 - 0.92	Pass
Lac *mmol/L*	1.6 - 2.2	Pass
Mg++ *mmol/L*	0.56 - 0.68	Pass

Level 5

	Spec	Pass/Fail
Na+ *mmol/L*	113.8 - 116.0	Pass
K+ *mmol/L*	6.14 - 6.26	Pass
Cl- *mmol/L*	97.9 - 99.9	Pass
Ca++ *mmol/L*	1.44 - 1.46	Pass
Glu *mg/dL*	279 - 291	Pass
BUN *mg/dL*	49.7 - 52.3	Pass
Creatinine *mg/dL*	6.47 - 6.73	Pass
Lac *mmol/L*	6.5 - 7.1	Pass
Mg++ *mmol/L*	1.09 - 1.21	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

09/19/2025
Date