nova biomedical

CERTIFICATE OF ANALYSIS

STP Prime Plus Auto QC Cartridge 105 Sample with Creat/BUN
Lot Number 24346047

Ref Number 57841
Exp Date 2026-06-02
Date of Manufacture 2024-12-02
UDI# (01)00385480578417(11)241202(17)260602(10)24346047

Level 1			Level 2			Level 3		
	Spec	Pass/Fail		Spec	Pass/Fail		Spec	Pass/Fail
pH	7.180 - 7.230	Pass	pH	7.350 - 7.420	Pass	pH	7.570 - 7.650	Pass
pCO2 *mmHg*	55.0 - 65.0	Pass	pCO2 *mmHg*	39.0 - 45.0	Pass	pCO2 *mmHg*	18.0 - 26.0	Pass
pO2 *mmHg*	58.0 - 68.0	Pass	pO2 *mmHg*	97.0 - 107.0	Pass	pO2 *mmHg*	135.0 - 149.0	Pass
tHb *g/dL*	18.0 - 22.0	Pass	tHb *g/dL*	13.0 - 16.0	Pass	tHb *g/dL*	5.5 - 8.5	Pass
COHb %	24.0 - 32.0	Pass	COHb %	17.0 - 23.0	Pass	COHb %	3.0 - 9.0	Pass
tBil *mg/dL*	18.0 - 24.0	Pass	tBil *mg/dL*	9.5 - 13.5	Pass	tBil *mg/dL*	4.0 - 8.0	Pass

Level 4			Level 5		
	Spec	Pass/Fail		Spec	Pass/Fail
Na+ *mmol/L*	141.9 - 144.7	Pass	Na+ *mmol/L*	114.0 - 116.4	Pass
K+ *mmol/L*	3.94 - 4.02	Pass	K+ *mmol/L*	6.13 - 6.25	Pass
Cl- *mmol/L*	126.6 - 129.2	Pass	Cl- *mmol/L*	96.9 - 98.9	Pass
Ca++ *mmol/L*	1.07 - 1.09	Pass	Ca++ *mmol/L*	1.47 - 1.49	Pass
Glu *mg/dL*	79 - 83	Pass	Glu *mg/dL*	265 - 275	Pass
BUN *mg/dL*	17.6 - 18.5	Pass	BUN *mg/dL*	50.7 - 53.3	Pass
Creatinine *mg/dL*	0.88 - 0.92	Pass	Creatinine *mg/dL*	6.47 - 6.73	Pass
Lac *mmol/L*	1.7 - 2.3	Pass	Lac *mmol/L*	6.7 - 7.3	Pass
Mg++ *mmol/L*	0.54 - 0.66	Pass	Mg++ *mmol/L*	1.06 - 1.18	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

Haneen Aldarwish

Approval

QC Inspector
Title

12/27/2024
Date