

CERTIFICATE OF ANALYSIS

Stat Profile Prime Ampuled Controls Lot Number 24123023 Ref Number 52714 Exp Date 2025-10-30

Date of Manufacture 2024-04-30

UDI# (01)00385480527149(11)240430(17)251030(10)24123023

	Level 1 L/N:	24121010	Level 2 L/N: 2412	21011		
Level 1 Exp Date: 2025-10-30			Level 2 Exp Date 2025	Level 2 Exp Date 2025-10-30		
	<u>Spec</u>	Pass/Fail	Spec Pass	s/Fail		
рН	7.110 - 7.190	Pass	pH 7.350 - 7.420 Pa	iSS		
pCO2 mmHg	55.0 - 65.0	Pass	pCO2 mmHg 39.0 - 45.0 Pa	ISS		
pO2 mmHg	58.0 - 68.0	Pass	pO2 mmHg 97.0 - 107.0 Pa	iSS		
Hct %	32 - 36	Pass	Hct % 49 - 53 Pa	ISS		
Na+ mmol/L	161.0 - 165.0	Pass	Na+ mmol/L 139.0 - 143.0 Pa	iSS		
K+ mmol/L	5.52 - 5.82	Pass	K+ mmol/L 3.64 - 3.84 Pa	ISS		
CI- mmol/L	124.3 - 133.3	Pass	Cl- mmol/L 98.0 - 106.0 Pa	ISS		
Ca++ mmol/L	1.50 - 1.58	Pass	Ca++ mmol/L 0.96 - 1.04 Pa	ISS		
Glu mg/dL	76 - 90	Pass	Glu mg/dL 195 - 225 Pa	ISS		
Lac mmol/L	0.8 - 1.2	Pass	Lac mmol/L 2.5 - 3.1 Pa	iSS		

Level 3 L/N: 24121012 Level 3 Exp Date: 2025-10-30

	<u>Spec</u>	Pass/Fail
рН	7.570 - 7.650	Pass
pCO2 mmHg	18.0 - 26.0	Pass
pO2 mmHg	135.0 - 149.0	Pass
Hct %	62 - 66	Pass
Na+ mmol/L	116.0 - 120.0	Pass
K+ mmol/L	1.70 - 2.00	Pass
CI- mmol/L	82.0- 90.0	Pass
Ca++ mmol/L	0.50 - 0.60	Pass
Glu mg/dL	297 - 347	Pass
Lac mmol/L	6.4 - 7.7	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. SO2 is traced to tonometry.

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

Approval

QC Inspector Title

5/29/2024 Date