

## **CERTIFICATE OF ANALYSIS**

Stat Profile Prime Ampuled Controls Lot Number 24074032 Ref Number 52714 Exp Date 2025-09-11

Date of Manufacture 2024-03-11

UDI# (01)00385480527149(11)240311(17)250911(10)24074032

	Level 1 L/N:	24071073	Level 2 L/N: 24071074	
Level 1 Exp Date: 2025-09-11			Level 2 Exp Date 2025-09-11	
	<u>Spec</u>	Pass/Fail	Spec Pass/Fail	
рН	7.110 - 7.190	Pass	pH 7.350 - 7.420 Pass	
pCO2 mmHg	55.0 - 65.0	Pass	pCO2 mmHg 39.0 - 45.0 Pass	
pO2 mmHg	58.0 - 68.0	Pass	pO2 mmHg 97.0 - 107.0 Pass	
Hct %	31 - 35	Pass	Hct % 49 - 53 Pass	
Na+ mmol/L	161.0 - 165.0	Pass	Na+ mmol/L 139.0 - 143.0 Pass	
K+ mmol/L	5.52 - 5.82	Pass	K+ mmol/L 3.64 - 3.84 Pass	
CI- mmol/L	124.3 - 133.3	Pass	CI- mmol/L 98.0 - 106.0 Pass	
Ca++ mmol/L	1.50 - 1.58	Pass	Ca++ mmol/L 0.96 - 1.04 Pass	
Glu mg/dL	76 - 90	Pass	Glu mg/dL 195 - 225 Pass	
Lac mmol/L	0.8 - 1.2	Pass	Lac mmol/L 2.5 - 3.1 Pass	

Level 3 L/N: 24071075 Level 3 Exp Date: 2025-09-11

	Spec	Pass/Fail
	Spec	<u>r ass/1 all</u>
pН	7.570 - 7.650	Pass
pCO2 mmHg	18.0 - 26.0	Pass
pO2 mmHg	135.0 - 149.0	Pass
Hct %	63 - 67	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 manufactu

Approval

QC Inspector Title

3/26/2024 Date