

## **CERTIFICATE OF ANALYSIS**

Nova StatStrip Lactate Linearity Solutions Levels 1 - 4 Lot Number 2824117990

2824117301

Level 1 L/N

Ref Number 47552 Exp Date 2026-10-26

Date of Manufacture 2024-04-26

2824117302

UDI# (01)00385480475525(11)240426(17)261026(10)2824117990

Level 2 L/N

Level 1 Exp Date	2026-10-26		Level 2 Exp Date	2026-10-26	
	Spec	Mean Result		Spec	Mean Result
Lactate mmol/L	0.5 - 0.7	0.6	Lactate mmol/L	2.2 - 2.6	2.4

Level 3 L/N 2824120303 Level 4 L/N 2824121304 Level 3 Exp Date 2026-10-29 Level 3 Exp Date 2026-10-30 Spec Mean Result Spec

Mean Result

5.9 - 6.7 Lactate mmol/L 6.2 Lactate mmol/L 15.5 - 18.0 17.3

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

Approval

QC Inspector

Title

5/31/2024 Date