



CERTIFICATE OF ANALYSIS

Nova StatStrip Lactate Linearity Solutions Levels 1 - 4
Lot Number 2822207990

Ref Number 47552
Exp Date 2025-01-26
Date of Manufacture 2022-07-26
UDI# (01)00385480475525(11)220726(17)250126(10)2822207990

Level 1 L/N	2822213301		Level 2 L/N	2822207302	
Level 1 Exp Date	2025-02-01		Level 2 Exp Date	2025-01-26	
	Spec	Mean Result		Spec	Mean Result
Lactate mmol/L	0.5 - 0.7	0.7	Lactate mmol/L	2.2 - 2.6	2.5
Level 3 L/N	2822214303		Level 4 L/N	2822208304	
Level 3 Exp Date	2025-02-02		Level 3 Exp Date	2025-01-27	
	Spec	Mean Result		Spec	Mean Result
Lactate mmol/L	5.9 - 6.7	6.3	Lactate mmol/L	15.5 - 18.0	17.0

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

Awishi M

Approval

QC Inspector

Title

10/13/2022

Date