



CERTIFICATE OF ANALYSIS

Nova StatStrip Lactate Linearity Solutions Levels 1 - 4
Lot Number 2824264990

Ref Number 47552
Exp Date 2027-03-20
Date of Manufacture 2024-09-20
UDI# (01)00385480475525(11)240920(17)270320(10)2824264990

Level 1 L/N	2824264301		Level 2 L/N	2824264302	
Level 1 Exp Date	2027-03-20		Level 2 Exp Date	2027-03-20	
	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	2824264303		Level 4 L/N	2824264304	
Level 3 Exp Date	2027-03-20		Level 3 Exp Date	2027-03-20	
	Spec	Mean Result		Spec	Mean Result
Lactate mmol/L	5.9 - 6.7	5.9	Lactate mmol/L	15.5 - 18.0	16.7

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

10/21/2024
Date