nova biomedical

CERTIFICATE OF ANALYSIS

Nova StatStrip Glucose/Ketone Linearity Kit — Ref Number 46950

Lot Number 0521018990 — Exp Date 2023-07-18

Date of Manufacture 2021-01-18

UDI# (01)00385480469500(11)210118(17)230718(10)0521018990

Level 1 L/N	0521025301		Level 2 L/N	0521032302	
Level 1 Exp Date	2023-07-25		Level 2 Exp Date	2023-08-01	
	Spec	Mean Result		Spec	Mean Result
Glucose mg/dL	16-22	20	Glucose mg/dL	57-65	62
			Ketone mmol/L	0.1-0.2	0.1

Level 3 L/N	0521035303		Level 4 L/N	0521018304	
Level 3 Exp Date	2023-08-04		Level 4 Exp Date	2023-07-18	
	Spec	Mean Result		Spec	Mean Result
Glucose mg/dL	105-125	118	Glucose mg/dL	275-325	308
Ketone mmol/L	0.7-1.0	0.9	Ketone mmol/L	2.5-3.5	3.2

Level 5 L/N	0521026305
Level 5 Exp Date	2023-07-26
	Spec	Mean Result
Glucose mg/dL	470-540	498
Ketone mmol/L	5.2-6.3	5.9

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. Analytes are traceable to NIST SRM Materials.

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

Anishi.M

Approval

QC Inspector
Title

4/1/2021
Date