

nova
biomedical
CERTIFICATE OF ANALYSIS

Nova StatStrip Glucose/Ketone Linearity Kit

Nova Reference 46950
LifeScan Reference 02313101
Lot Number 0525171990

Exp Date 2027-12-20
Date of Manufacture 2025-06-20
UDI#(01)00385480469500(11)250620(17)271220(10)0525171990

Level 1 L/N 0525171301
Exp Date 2027-12-20

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	16 - 22	21

Level 2 L/N 0525171302
Exp Date 2027-12-20

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	57 - 65	61
Ketone mmol/L	0.1 - 0.2	0.1

Level 3 L/N 0525171303
Exp Date 2027-12-20

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	105 - 125	114
Ketone mmol/L	0.7 - 1.1	0.9

Level 4 L/N 0525174304
Exp Date 2027-12-23

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	275 - 325	304
Ketone mmol/L	2.5 - 3.7	3.5

Level 5 L/N 0525174305
Exp Date 2027-12-23

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	470 - 540	490
Ketone mmol/L	5.2 - 6.3	6.2

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

09/19/2025
Date