

*nova*  
*biomedical*  
CERTIFICATE OF ANALYSIS

**Nova StatStrip Glucose/Ketone Linearity Kit**

Nova Reference 46950  
LifeScan Reference 02313101  
Lot Number 0523027990

Exp Date 2025-07-27  
Date of Manufacture 2023-01-27  
UDI#(01)00385480469500(11)230127(17)250727(10)0523027990

Level 1 L/N 0523039301  
Exp Date 2025-08-08

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

Level 2 L/N 0523030302  
Exp Date 2025-07-30

	<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 0523040303  
Exp Date 2025-08-09

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	105 - 125	110
Ketone mmol/L	0.7 - 1.1	0.9

Level 4 L/N 0523027304  
Exp Date 2025-07-27

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	275 - 325	298
Ketone mmol/L	2.5 - 3.7	3.1

Level 5 L/N 0523039305  
Exp Date 2025-08-08

	<u>Spec</u>	<u>Mean Result</u>
Glucose mg/dL	470 - 540	494
Ketone mmol/L	5.2 - 6.3	5.8

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

*Auishi M*

Approval

QC Inspector  
Title

05/23/2023  
Date