

*nova*  
*biomedical*  
CERTIFICATE OF ANALYSIS

**Nova StatStrip Glucose and  $\beta$ -Ketone Control Solution Level 3**

Nova Reference 46949

Exp Date 2027-09-14

LifeScan Reference 02313001

Date of Manufacture 2025-03-14

Lot Number 0425073303

UDI# (01)00385480469494(11)250314(17)270914(10)0425073303

|               | <u>Spec</u> | <u>Mean Result</u> |
|---------------|-------------|--------------------|
| Glucose mg/dL | 275 - 325   | 302                |
| Ketone mmol/L | 2.5 - 3.7   | 3.5                |

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: The process for assigning values to Nova Biomedical Quality Control and Linearity Solutions utilizes multiple sources of test data inputs to establish the ranges for each analyte in each lot, which may result in small lot-to-lot variation in insert range values.

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



Approval

QC Inspector

Title

4/3/2025

Date