

CERTIFICATE OF ANALYSIS

Nova StatStrip Glucose Linearity Kit Lot Number 0524068990 Ref Number 42173 Exp Date 2026-09-08

Date of Manufacture 2024-03-08

UDI# (01)00385480421737(11)240308(17)260908(10)0524068990

Level 2 Exp Date 2026-09-08 Spec Mean Result

0524068302

301

Glucose mg/dL 57 - 65 63

Level 2 L/N

 Level 3 L/N
 0524068303
 Level 4 L/N
 0524072304

 Level 3 Exp Date
 2026-09-08
 Level 4 Exp Date
 2026-09-12

 Spec
 Mean Result
 Spec
 Mean Result

Glucose mg/dL 105 - 125 113 Glucose mg/dL 275 - 325

Level 5 L/N 0524072305 Level 5 Exp Date 2026-09-12

<u>Spec</u> <u>Mean Result</u> Glucose mg/dL 470 - 540 506

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

Auishi.M

Approval

QC Inspector Title

4/4/2025 Date