



CERTIFICATE OF ANALYSIS

Nova StatStrip Glucose Linearity Kit
Lot Number 0523069990

Ref Number 42173

Exp Date 2025-09-10

Date of Manufacture 2023-03-10

UDI# (01)00385480421737(11)230310(17)250910(10)0523069990

Level 1 L/N 0523069301
Level 1 Exp Date 2025-09-10
Spec Mean Result
Glucose mg/dL 16 - 22 18

Level 2 L/N 0523073302
Level 2 Exp Date 2025-09-14
Spec Mean Result
Glucose mg/dL 57 - 65 59

Level 3 L/N 0523069303
Level 3 Exp Date 2025-09-10
Spec Mean Result
Glucose mg/dL 105 - 125 111

Level 4 L/N 0523074304
Level 4 Exp Date 2025-09-15
Spec Mean Result
Glucose mg/dL 275 - 325 303

Level 5 L/N 0523069305
Level 5 Exp Date 2025-09-10
Spec Mean Result
Glucose mg/dL 470 - 540 491

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

6/12/2023

Date