



CERTIFICATE OF ANALYSIS

Nova StatStrip Glucose Linearity Kit
Lot Number 0524232990

Ref Number 42173
Exp Date 2027-02-19
Date of Manufacture 2024-08-19
UDI# (01)00385480421737(11)240819(17)270219(10)0524232990

Level 1 L/N 0524232301
Level 1 Exp Date 2027-02-19
Spec Mean Result
Glucose mg/dL 16 - 22 19

Level 2 L/N 0524232302
Level 2 Exp Date 2027-02-19
Spec Mean Result
Glucose mg/dL 57 - 65 60

Level 3 L/N 0524233303
Level 3 Exp Date 2027-02-20
Spec Mean Result
Glucose mg/dL 105 - 125 115

Level 4 L/N 0524234304
Level 4 Exp Date 2027-02-21
Spec Mean Result
Glucose mg/dL 275 - 325 300

Level 5 L/N 0524235305
Level 5 Exp Date 2027-02-22
Spec Mean Result
Glucose mg/dL 470 - 540 503

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

Approval

QC Inspector
Title

9/27/2024
Date