

## **CERTIFICATE OF ANALYSIS**

## Nova StatStrip Glucose and β-Ketone Control Solution Level 3 Ref Number 46949 Lot Number 0421018303 Exp Date 2023-07-18 Date of Manufacture 2021-01-18 UDI# (01)00385480469494(11)210118(17)230718(10)0421018303

|               | <u>Spec</u> | <u>Mean Result</u> |
|---------------|-------------|--------------------|
| Glucose mg/dL | 275 - 325   | 300                |
| Ketone mmol/L | 2.5 - 3.5   | 3.2                |

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.

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

Approval

QC Inspector Title

<u>2/4/2021</u> Date