

CERTIFICATE OF ANALYSIS

Nipro Glucose and β-Ketone Control Solution Level 2 Lot Number 0423040302

Ref Number 11-116 Exp Date 2025.08.31

	<u>Spec</u>	Mean Result
Glucose mg/dL	105 - 125	116
Ketone mmol/L	0.7 - 1.1	0.8

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

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Approval

QC Inspector Title

<u>3/10/2023</u> Date