



CERTIFICATE OF ANALYSIS

Nipro Glucose and β -Ketone Control Solution Level 3

Lot Number 0415120303

Ref Number 11-117

Exp Date 2017-10

	Spec	Mean Result
Glucose mg/dL	285-310	302
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 21 CFR-Part 820, Quality System Regulation (QSR), Current Good Manufacturing Practice (cGMP) and EN ISO 13485:2012, Medical Devices, Quality Management Systems for in Vitro Diagnostic devices, and conforms to the indicated test specifications.

A handwritten signature in dark ink, appearing to read "Joyce Amara", written in a cursive style.

Approval

QC Supervisor

Title

5/28/2015

Date

CONFIDENTIAL