



CERTIFICATE OF ANALYSIS

Nipro Glucose and β -Ketone Control Solution Level 1
Lot Number 0415051301

Ref Number 11-115
Exp Date 2017-08

	Spec	Mean Result
Glucose mg/dL	58-63	61
Ketone mmol/L	0.1-0.2	0.1

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 cursive script, appearing to read "Joyce Amara".

Approval

QC Supervisor

Title

3/19/2015

Date

CONFIDENTIAL