



CERTIFICATE OF ANALYSIS

Nipro Glucose and β -Ketone Control Solution Level 2

Lot Number 0415051302

Ref Number 11-116

Exp Date 2017-08

	Spec	Mean Result
Glucose mg/dL	110-120	114
Ketone mmol/L	0.7-1.0	0.8

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".

Approval

QC Supervisor

Title

3/23/2015

Date

CONFIDENTIAL