



CERTIFICATE OF ANALYSIS

Nova StatStrip Glucose/Ketone Linearity Kit
Lot Number 0513098990

Ref Number 46950
Exp Date 2015-10

Level 1 L/N 0513092301
Level 1 Exp Date

	Spec	Mean Result
Glucose mg/dL	16-28	17

Level 2 L/N 0513092302
Level 2 Exp Date

	Spec	Mean Result
Glucose mg/dL	46-76	66
Ketone mmol/L	0.1-0.5	0.1

Level 3 L/N 0513094303
Level 3 Exp Date

	Spec	Mean Result
Glucose mg/dL	90-130	118
Ketone mmol/L	0.5-1.2	1.1

Level 4 L/N 0513094304
Level 4 Exp Date

	Spec	Mean Result
Glucose mg/dL	260-330	307
Ketone mmol/L	2.2-3.8	3.5

Level 5 L/N 0513103305
Level 5 Exp Date

	Spec	Mean Result
Glucose mg/dL	410-590	487
Ketone mmol/L	4.4-7.0	6.2

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. Analytes are traceable to NIST SRM Materials.

Approval

QC Supervisor

Title

5/20/2013

Date

CONFIDENTIAL