

CERTIFICATE OF ANALYSIS

Bioprofile 400/Basic/100+ Glucose Sensor Lot Number 15189006 Part Number 37641

Exp Date 7/31/2017

 Spec*
 Pass/Fail

 Slope
 5.0-60.0
 Pass

 Biopro Ctl L1
 0.75-1.25
 Pass

 Biopro Ctl L3
 12.75-17.25
 Pass

This product is certified to have been manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U. S. A. in accordance with ISO 9001:2008, Quality Management System Requirements and current Good Manufacturing Practices (cGMP), and conforms to the indicated test specifications.

*Note: The process for assigning values to Nova Biomedical Quality Control and Linearity Solutions utilizes multiple sources of test data inputs to establish the ranges for each analyte in each lot, which may result in small lot-to-lot variation in insert range values.

Approval

QC Supervisor

Title

7/29/2015

Date

CONFIDENTIAL

Joyce ansara