

OI 947 Page 21 of 26 Rev. Z Viald and Packaged Test Strip Release Nova Max Int'l

Attachment 5 (Mio/Lx)



Quality Systems Department
Certificate of Analysis

Nova Biomedical certifies that the following Nova Biomedical Product was manufactured in accordance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) standards and that these products were tested at the factory and meets all Nova Biomedical standards for test specifications, performance, quality and safety.

Description: TEST STRIP 50 CT BOXED LX DE
Reference Number: 38879
Part Number / BOM Rev.: 44518 /C
Lot Number: 3219063249
Expiration Date: 2021/03/31
Normal Control Range: SEE ATTACHMENT
High Control Range: SEE ATTACHMENT
Quantity: 10,332
Date of Release: 5/9 5/16/19
8th 5/16/19

Target Level (mg/dL)	YSI Mean (mg/dL)	Mean (mg/dL)	SD (mg/dL) /CV (%)	CV /SD Specification	P/F
30-50	49.6	48	3.0	≤9 mg/dL (SD)	P
51-110	102.0	96	5.0	Fail If both CV of this level and combined CV (L2-L5) >5.0%	P
111-150	142.0	136	3.4	Fail If both CV of this level and combined CV (L2-L5) >5.0%	P
151-250	234.5	225	4.6	Fail If both CV of this level and combined CV (L2-L5) >5.0%	P
251-400	368.5	358	4.5	Fail If both CV of this level and combined CV (L2-L5) >5.0%	P
Total within ISO Zone and %: <u>179, 99.4%</u> (per ISO 15197:2013)					Total within ISO Zone ≥95% P

NOTE: Test data in table above taken from completed and approved Data Sheets from TP 139-868 for this lot number.

Mar Brune

Quality Control Manager

Title: QC Manager

Date: 5/16/19

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02453

Data Sheet #7 – Assignment of Control Ranges (Lx)Test Strips Lot # 3219063249Production Date: 3/4-5/2019**LX** Control Ranges:

(+/- 15%)

Normal (115) 98 – 132 mg/dL or

(6.4) 5.4 – 7.3 mmol/L

High (328) 279 – 377 mg/dL or

(18.2) 15.5 – 20.9 mmol/L

ADD'L LX Control Ranges:

(+/- 11% (Germany only) Normal (115) 103 – 127 mg/dL or ✓

Per Rilibak Regulation (6.4) 5.7 – 7.0 mmol/L ✓

High (328) 292 – 364 mg/dL or ✓

(18.2) 16.2 – 20.2 mmol/L ✓

Note: mg/dL X .0555 = mmol/LAdvanced Manufacturing Approval: M. Hume Date 3/14/19Reviewer: MacBryne Date 3/14/19

(For Incoming Inspection only)

Attach Vial Label below:

N
A

Incoming Inspection Approval: _____ Date _____

Q.C. Approval: _____ Date _____