

OI-932

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Rev. W

Packaged Test Strip Release

Nova Max & Nova Vet

Attachment 2



**Certificate of Conformance & Analysis**

Nova Biomedical certifies that the following Nova Max Product has been built and tested in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) and meets Nova Biomedical product specifications.

Description: PACK RETAIL 50 CT NMAX

Part Number: 4 3 4 3 7

BOM Rev.: E

Lot Number: 1 0 2 0 2 2 2 2 9 2

Expiration Date: 2 0 2 4 - 1 0 - 1 9

Date of Manufacture: 2 0 2 2 - 1 0 - 1 9

UDI: (01)20385480 4 3 4 3 7 3

(11) 2 2 1 0 1 9

(17) 2 4 1 0 1 9

(10) 1 0 2 0 2 2 2 2 9 2

Quantity: 41,631

Date of Release: 2 0 2 2 - 1 1 - 0 7

Release Test Results Summary					
Target Level (mg/dL)	YSI Mean (mg/dL)	Mean (mg/dL)	SD (mg/dL) /CV (%)	SD/CV Specification	P/F
40-80	56.6	61	2.7	≤ 9 mg/dL	P
120-180	174.0	169	3.2	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
220-300	297.8	290	3.6	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
320-440	426.8	420	4.0	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
450-550	488.5	478	3.2	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
Total within ISO Zone and %: <u>360 / 100.0%</u> (per ISO15197:2013)				Total within ISO Zone ≥95%	P

**NOTE:** Test data in table above taken from completed and approved Data Sheets from TP 139-501 for this lot number.

Mar Brown  
Quality Control Manager Signature  
Title: QC Manager  
Date: 11/7/2022

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