

OI-932

Page 7 of 10

Rev. W

Packaged Test Strip Release

Nova Max & Nova Vet

Attachment 2

nova
biomedical

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: Nova Max 50ct.

Part Number: 4 3 5 2 3

BOM Rev.: F

Lot Number: 1 0 2 0 4 2 3 1 9 8

Expiration Date: 2 0 2 5 - 0 7 - 1 7

Date of Manufacture: 2 0 2 3 - 0 7 - 1 7

UDI: (01)20385480 4 3 5 2 3 3

(11) 2 3 0 7 1 7

(17) 2 5 0 7 1 7

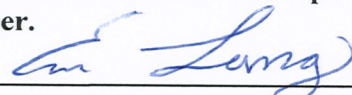
(10) 1 0 2 0 4 2 3 1 9 8

Quantity: 5,040

Date of Release: 2 0 2 3 - 0 8 - 2 3

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	<u>65.8</u>	<u>67</u>	<u>3.3</u>	≤ 9 mg/dL	<u>P</u>
120-180	<u>177.3</u>	<u>174</u>	<u>3.1</u>	Fail If Both CV of this level and combined CV (L2-L5) $>5.0\%$	<u>P</u>
220-300	<u>280.3</u>	<u>275</u>	<u>3.4</u>	Fail If Both CV of this level and combined CV (L2-L5) $>5.0\%$	<u>P</u>
320-440	<u>394.3</u>	<u>386</u>	<u>3.5</u>	Fail If Both CV of this level and combined CV (L2-L5) $>5.0\%$	<u>P</u>
450-550	<u>508.0</u>	<u>477</u>	<u>3.3</u>	Fail If Both CV of this level and combined CV (L2-L5) $>5.0\%$	<u>P</u>
Total within ISO Zone and %: <u>360/100%</u> (per (ISO15197:2013))				Total within ISO Zone $\geq 95\%$	<u>P</u>

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



Quality Control Manager Signature

Title: _____

Date: 8/24/23

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454