

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: Pack DME 50 count NMax

Part Number: 43 523

BOM Rev.: F

Lot Number: 1020222157

Expiration Date: 2024-06-06

Date of Manufacture: 2022-06-06

UDI: (01)20385480 43 5233

(11) 220606

(17) 240606

(10) 1020222157

Quantity: 11,970

Date of Release: 2022-06-15

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>70.5</u>	<u>64</u>	<u>3.4</u>	≤ 9 mg/dL	<u>P</u>
120-180	<u>172.0</u>	<u>163</u>	<u>3.0</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
220-300	<u>283.0</u>	<u>282</u>	<u>3.7</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
320-440	<u>398.5</u>	<u>397</u>	<u>2.6</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
450-550	<u>509.8</u>	<u>508</u>	<u>3.2</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
Total within ISO Zone and %: <u>359 / 99.7</u>			(per (ISO15197:2013))		Total within ISO Zone <u>≥95%</u>

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

Marie Brune
Quality Control Manager Signature

Title: Quality Manager

Date: 6/15/2022

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454