

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 150 Count Nmax

Part Number: 43437

BOM Rev.: F

Lot Number: 1020223226

Expiration Date: 2025-08-14

Date of Manufacture: 2023-08-14

UDI: (01)20385480 434373

(11) 230814

(17) 250814

(10) 1020223226

Quantity: 43,591

Date of Release: 2023-08-31

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>63</u>	<u>58</u>	<u>2.2</u>	≤ 9 mg/dL	<u>P</u>
120-180	<u>157.8</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>264.5</u>	<u>261</u>	<u>3.2</u>	Fail If Both CV of this level and combined CV (L2-L5) $>5.0\%$	<u>P</u>
320-440	<u>383.8</u>	<u>378</u>	<u>3.6</u>	Fail If Both CV of this level and combined CV (L2-L5) $>5.0\%$	<u>P</u>
450-550	<u>504.5</u>	<u>481</u>	<u>3.0</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</u> <u>100%</u>			(per (ISO15197:2013))		Total within ISO Zone <u>P</u> $\geq 95\%$

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

Marc Browne

Quality Control Manager Signature
Title: Quality Mgr
Date: 8/31/2023

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