

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 DME 50 CT NOVA MAX

Part Number: 43523

BOM Rev.: F

Lot Number: 102022230

Expiration Date: 2024-08-18

Date of Manufacture: 2022-08-18

UDI: (01)20385480 435233

(11) 220818

(17) 240818

(10) 102022230

Quantity: 7,740

Date of Release: 2022-09-01

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	76.1	77	3.5	≤ 9 mg/dL	P
120-180	172.0	161	2.5	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
220-300	290.3	270	3.1	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
320-440	413.0	389	3.4	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
450-550	517.8	483	3.6	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
Total within ISO Zone and %: <u>359,99.7%</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.

Marc Broome

Quality Control Manager Signature

Title: In Quality Mgr

Date: 9-1-2022

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