

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: 4 3 5 2 3

BOM Rev.: F

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 5 2 3 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: 8,460

Date of Release: 2 0 2 3 - 0 5 - 2 6

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 %:			(per (ISO15197:2013))	Total within ISO Zone $\geq 95\%$	P
<u>360, 100.0%</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: Sr Mfg Manager

Date: 5/25/23

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