

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: Nova Max Kit Packaging  
 Part Number: 43604  
 BOM Rev.: A  
 Lot Number: 1020423131  
 Expiration Date: 2025-05-11  
 Date of Manufacture: 2023-05-11  
 UDI: (01)20385480 436042  
 (11) 230511  
 (17) 250511  
 (10) 1020423131  
 Quantity: 1465  
 Date of Release: 2023-05-24

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	63.3	66	2.9	≤ 9 mg/dL	P
120-180	177.3	172	3.6	Fail If Both CV of this level and combined CV (L2-L5) > 5.0%	P
220-300	298.8	291	3.0	Fail If Both CV of this level and combined CV (L2-L5) > 5.0%	P
320-440	422.5	419	3.7	Fail If Both CV of this level and combined CV (L2-L5) > 5.0%	P
450-550	546.5	530	2.9	Fail If Both CV of this level and combined CV (L2-L5) > 5.0%	P
Total within ISO Zone and %: <u>360/100%</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 Browne  
 Quality Control Manager Signature  
 Title: Dr Quality Mgr  
 Date: 5/24/2023

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