

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 solut Nmax  
 Part Number: 43523  
 BOM Rev.: E  
 Lot Number: 1020225224  
 Expiration Date: 2027-08-12  
 Date of Manufacture: 2025-08-12  
 UDI: (01)20385480 435233  
       (11) 250812  
       (17) 270812  
       (10) 1020225224  
 Quantity: 5.022  
 Date of Release: 2025-20-25

Release Test Results Summary					
Target Level (mg/dL)	YSI Mean (mg/dL)	Mean (mg/dL)	SD (mg/dL) /CV (%)	SD/CV Specification	P/F
30-50	43.8	44	4.0	≤ 4 mg/dL	P
51-110	90.3	87	3.1	≤6.0%	P
111-150	136.3	137	2.9	≤5.0%	P
151-250	228.3	225	3.4	≤5.0%	P
251-400	353.3	351	2.9	≤5.0%	P
Accuracy Criteria 1: Total within +/-11.3 mg/dL or +/- 15% of reference method: <u>99.8%</u>				Specification: ≥95%	P
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 20% of reference method: <u>100%</u>				Specification: ≥99%	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: Jr Q.C. Manager

Date: 8/20/25