

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 50 count NMAX  
 Part Number: 43437  
 BOM Rev.: E  
 Lot Number: 1020226048  
 Expiration Date: 2028-02-17  
 Date of Manufacture: 2026-02-17  
 UDI: (01)20385480 434373  
 (11) 260217  
 (17) 280217  
 (10) 1020226048  
 Quantity: 40,482  
 Date of Release: 2026-02-27

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	49.8	49	3.6	≤ 4 mg/dL	P
51-110	102.8	101	4.7	≤6.0%	P
111-150	135.0	135	3.4	≤5.0%	P
151-250	221.8	224	3.8	≤5.0%	P
251-400	346.5	354	2.7	≤5.0%	P
Accuracy Criteria 1: Total within +/-11.3 mg/dL or +/- 15% of reference method:				Specification: ≥95%	P
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 20% of reference method:				Specification: ≥99%	P

**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: \_\_\_\_\_

Date: 2/27/24