

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: Test strip 10ct Labeled Nmax  
 Part Number: 43604  
 BOM Rev.: A  
 Lot Number: 1020225224  
 Expiration Date: 2027-08-12  
 Date of Manufacture: 2025-08-12  
 UDI: (01)20385480436042  
 (11)250812  
 (17)270812  
 (10)1020225224  
 Quantity: 1000  
 Date of Release: 2025-08-19

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.

Quality Control Manager Signature  
 Title: Sr. Mfg. Manager  
 Date: 8/19/25