

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.: F
 Lot Number: 1020225224
 Expiration Date: 2027-08-12
 Date of Manufacture: 2025-08-12
 UDI: (01)20385480 434373
 (11) 250812
 (17) 270812
 (10) 1020225224
 Quantity: 24,534
 Date of Release: 2025-08-21

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.

Marie Browne

Quality Control Manager Signature
 Title: Quality Mgr
 Date: 8-21-25