

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: 1020225043

Expiration Date: 2027-02-12

Date of Manufacture: 2025-02-12

UDI: (01)20385480 434373

(11) 250212

(17) 270212

(10) 1020225043

Quantity: 30,240

Date of Release: 2025-02-24

Release Test Results Summary					
Target Level (mg/dL)	YSI Mean (mg/dL)	Mean (mg/dL)	SD (mg/dL) /CV (%)	SD/CV Specification	P/F
30-50	45.1	45	2.9	≤ 4 mg/dL	P
51-110	92.9	89	3.1	≤6.0%	P
111-150	139.3	140	3.5	≤5.0%	P
151-250	229.8	224	3.1	≤5.0%	P
251-400	372.5	367	3.5	≤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.

Marc Broome
Quality Control Manager Signature
Title: QC Manager

Date: 2/24/25

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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