

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 50ct Count NMAX

Part Number: 4 3 4 3 7

BOM Rev.: F

Lot Number: 1 0 2 0 2 2 3 2 6 1

Expiration Date: 2 0 2 5 - 0 9 - 1 8

Date of Manufacture: 2 0 2 3 - 0 9 - 1 8

UDI: (01)20385480 4 3 4 3 7 3

(11) 2 3 0 9 1 8

(17) 2 5 0 9 1 8

(10) 1 0 2 0 2 2 3 2 6 1

Quantity: 37,800

Date of Release: 2 0 2 3 - 0 9 - 2 8

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	44.2	44	3.9	≤ 4 mg/dL	P
51-110	71.4	69	4.9	≤6.0%	P
111-150	137.0	135	4.2	≤5.0%	P
151-250	241.5	232	4.4	≤5.0%	P
251-400	392.8	391	3.8	≤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>100.0 %</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:

QC Manager

Date:

10/19/23

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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