

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 DME 50 ct Nmax
 Part Number: 43523
 BOM Rev.: F
 Lot Number: 1020624303
 Expiration Date: 2026-10-29
 Date of Manufacture: 2024-10-29
 UDI: (01)20385480 435233
 (11) 241029
 (17) 261029
 (10) 1020624303
 Quantity: 7,560
 Date of Release: 2024-11-18

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	48.8	49	3.5	≤ 4 mg/dL	P
51-110	91.7	85	3.8	≤6.0%	P
111-150	132.5	129	4.1	≤5.0%	P
151-250	248.8	239	4.4	≤5.0%	P
251-400	394.3	382	4.1	≤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

Title: QC Manager

Date: 11/18/24