

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 SO count NMax
 Part Number: 43523
 BOM Rev.: F
 Lot Number: 1020224199
 Expiration Date: 2026-07-17
 Date of Manufacture: 2024-07-17
 UDI: (01)20385480 435233
 (11) 240717
 (17) 260717
 (10) 1020224199
 Quantity: 9,234
 Date of Release: 2024-07-31

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	49.1	48	3.9	≤ 4 mg/dL	P
51-110	91.3	87	3.9	≤6.0%	P
111-150	142.0	139	4.2	≤5.0%	P
151-250	235.8	228	3.6	≤5.0%	P
251-400	394.8	387	3.2	≤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.

Mark Brown

Quality Control Manager Signature

Title: QC Manager

Date: 7/31/24

