

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 Count NMAX

Part Number: 43523

BOM Rev.: F

Lot Number: 1020625045

Expiration Date: 2027-02-14

Date of Manufacture: 2025-02-14

UDI: (01)20385480 435233

(11) 250214

(17) 270214

(10) 1020625045

Quantity: 11,688

Date of Release: 2025-02-25

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	<u>44.5</u>	<u>44</u>	<u>3.2</u>	≤ 4 mg/dL	<u>P</u>
51-110	<u>98.6</u>	<u>96</u>	<u>4.3</u>	$\leq 6.0\%$	<u>P</u>
111-150	<u>141.3</u>	<u>140</u>	<u>3.4</u>	$\leq 5.0\%$	<u>P</u>
151-250	<u>230.0</u>	<u>236</u>	<u>2.5</u>	$\leq 5.0\%$	<u>P</u>
251-400	<u>357.5</u>	<u>355</u>	<u>3.0</u>	$\leq 5.0\%$	<u>P</u>
Accuracy Criteria 1: Total within +/-11.3 mg/dL or +/- 15% of reference method:				Specification: $\geq 95\%$	<u>P</u>
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 20% of reference method:				Specification: $\geq 99\%$	<u>P</u>

NOTE: Test data in table above taken from completed and approved Data Sheets from TP 139-501 for this lot number.

Quality Control Manager Signature

Title: SK MA / Manager

Date: 2/25/25

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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