

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: 100CT CA NOVAMAX
 Part Number: 43955
 BOM Rev.: C
 Lot Number: 1020423198
 Expiration Date: 2025-07-17
 Date of Manufacture: 2023-07-17
 UDI: (01)20385480439552
 (11)230717
 (17)250717
 (10)1020423198
 Quantity: 4,720
 Date of Release: 2023-07-25

Release Test Results Summary					
Target Level (mg/dL)	YSI Mean (mg/dL)	Mean (mg/dL)	SD (mg/dL) /CV (%)	SD/CV Specification	P/F
40-80	65.8	67	3.3	≤ 9 mg/dL	P
120-180	177.3	174	3.1	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
220-300	280.3	275	3.4	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
320-440	396.3	386	3.5	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
450-550	508.0	477	3.3	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
Total within ISO Zone and %: <u>300 100%</u> (per (ISO15197:2013)				Total within ISO Zone ≥95%	P

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

Mar Browne

Title: Quality Control Manager Signature

Date: 7/25/2023

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

