

OI-932

Page 7 of 10

Rev. W

Packaged Test Strip Release

Nova Max & Nova Vet

Attachment 2

nova
biomedical

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.: E

Lot Number: 1020222292

Expiration Date: 2024-10-19

Date of Manufacture: 2022-10-19

UDI: (01)20385480 435233

(11) 221019

(17) 241019

(10) 1020222292

Quantity: 10,026

Date of Release: 2022-11-04

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	56.6	61	2.7	≤ 9 mg/dL	P
120-180	174.0	169	3.2	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
220-300	297.8	290	3.6	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
320-440	426.8	420	4.0	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
450-550	488.5	478	3.2	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	P
Total within ISO Zone and %: <u>360 / 100.0%</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.

Marc Browne

Title: Quality Control Manager Signature

Date: 11/4/2022

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454