

OI-932

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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 RETAIL 40 COUNT NMAX

Part Number: 43437

BOM Rev.: E

Lot Number: 1020222157

Expiration Date: 2024-06-06

Date of Manufacture: 2022-06-06

UDI: (01)20385480 434373

(11) 220606

(17) 240606

(10) 1020222157

Quantity: 37,818

Date of Release: 2022-06-16

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	70.5	64	3.4	≤ 9 mg/dL	✓
120-180	172.0	163	3.0	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	✓
220-300	283.0	282	3.7	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	✓
320-440	398.5	397	2.6	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	✓
450-550	509.8	508	3.2	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	✓
Total within ISO Zone and %: 359, 99.7%		(per (ISO15197:2013)		Total within ISO Zone ≥95%	✓

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

Mar Broome

Quality Control Manager Signature

Title:

Date:

QC Manager

6/16/2022

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454