

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 RETAIL 50 COUNT NMAX

Part Number: 43437

BOM Rev.: F

Lot Number: 1020423198

Expiration Date: 2025-07-17

Date of Manufacture: 2023-07-17

UDI: (01)20385480 434373

(11) 230717

(17) 250717

(10) 1020423198

Quantity: 22,058

Date of Release: 2023-07-26

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>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 Broome

Quality Control Manager Signature

Title: In QC Manager

Date: 7/26/2023

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