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Vialed and Packaged Test Strip Release

Test Strips



## **CERTIFICATE OF COMPLIANCE**

This product has been manufactured in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

Customer:		NIA
Description:		
Description:		TEST STRIPS, STATSTRIP TM
		GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:		42214
Nova Biomedical P/N		51493
Target Range (mg/dL) SD(mg/dL) /CV (%)		
30-50	≤ 4 mg/dL	PASS \ FAIL
51-110	≤ 6.0%	PASS FAIL
111-150	≤ 5.0%	PASS FAIL
151-250	≤ 5.0%	PASS FAIL
251-400	≤ 5.0%	PASS FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method $\geq$ 95%		PASS FAIL
Accuracy Criteria 2: Total within $\pm$ -15 mg/dL or $\pm$ -15% of reference method $\geq$ 98%		PASS / FAIL
Qty:		10,720
Lot No.		0324162309
Mfg. Date:		2024 - 06 - 10
Expiration Date:		2026-12-10
Unique Device Identifier (UDI):		(01)20385480422141
		(11) <u>2 4 0 6 1 0</u>
		(17) <u>26 12 10</u>
11 1		(10) 0 3 2 4 1 6 2 3 0 9
IVan Bon	Ane	7/9/2024
Quality Control Mana	ger	Date

Nova Biomedical Corporation

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