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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:	TEST STRIPS, STATSTRIP TM GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:	42214
Nova Biomedical P/N	55890
Target Range (mg/dL) SD(mg/dL) /CV (%)	
$30-50$ $\leq 4 \text{ mg/dL}$	PASS) FAIL
51-110 ≤ 6.0%	PASS) FAIL
111-150 ≤ 5.0%	PASS FAIL
$151-250 \leq 5.0\%$	(PASS) FAIL
251 <b>-</b> 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 +/-15 mg/dL or +/-15% of reference method ≥ 98%	PASS/ FAIL
Qty:	4,689
Lot No.	0325113249
Mfg. Date:	2025-04-23
Expiration Date:	2027-04-23
Unique Device Identifier (UDI):	$\begin{array}{c} (01)20385480422141 \\ (11) \underline{2} \ \underline{5} \ \underline{0} \ \underline{4} \ \underline{2} \ \underline{3} \\ (17) \ \underline{2} \ \underline{7} \ \underline{0} \ \underline{4} \ \underline{2} \ \underline{3} \\ (10) \ \underline{0} \ \underline{3} \ \underline{3} \ \underline{5} \ \underline{1} \ \underline{1} \ \underline{3} \ \underline{3} \ \underline{4} \ \underline{9} \end{array}$
Margroene	5/2/25
Quality Control Manager Date	

Nova Biomedical Corporation

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