

OI-922

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Rev. BJ

Vialed and Packaged Test Strip Release

Test Strips

*nova*  
biomedical

## 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™ GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:	42214
Nova Biomedical P/N	55890
Target Range (mg/dL)      SD(mg/dL) /CV (%)	
30-50                              ≤ 4 mg/dL	<u>PASS</u> / FAIL
51-110                             ≤ 6.0%	<u>PASS</u> / FAIL
111-150                          ≤ 5.0%	<u>PASS</u> / FAIL
151-250                          ≤ 5.0%	<u>PASS</u> / FAIL
251-400                          ≤ 5.0%	<u>PASS</u> / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%	<u>PASS</u> / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%	<u>PASS</u> / FAIL
Qty:	1,470
Lot No.	0324011249
Mfg. Date:	2024-01-11
Expiration Date:	2026-01-11
Unique Device Identifier (UDI):	(01)20385480422141 (11) <u>240111</u> (17) <u>260111</u> (10) <u>0324011249</u>

Quality Control Manager

Date 1/19/24

Nova Biomedical Corporation

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