



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	(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 ≥ 95%	(PASS) / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%	(PASS) / FAIL
Qty:	3,360
Lot No.	0325027249
Mfg. Date:	2025-01-27
Expiration Date:	2027-01-27
Unique Device Identifier (UDI):	(01)20385480422141 (11) <u>250127</u> (17) <u>270127</u> (10) <u>0325027249</u>

Quality Control Manager

Date

Nova Biomedical Corporation

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