



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:	2,854	
Lot No.	0325133249	
Mfg. Date:	2025-05-13	
Expiration Date:	2027-05-14	
Unique Device Identifier (UDI):	(01)20385480422141 (11) <u>2 5 0 5 1 3</u> (17) <u>2 7 0 5 1 4</u> (10) <u>0 3 2 5 1 3 3 2 4 9</u>	

Marc Bowdane Date 6/17/25
 Quality Control Manager

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454