



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:	N/A	
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:	5,803	
Lot No.	0324197249	
Mfg. Date:	2024-07-15	
Expiration Date:	2026-07-15	
Unique Device Identifier (UDI):	(01)20385480422141 (11) <u>240715</u> (17) <u>260715</u> (10) <u>0324197249</u>	

Marc Bovee
 Quality Control Manager

8/6/2024
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454