



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	51493	
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:	8,610	
Lot No.	0325209309	
Mfg. Date:	2025-07-28	
Expiration Date:	2028-01-28	
Unique Device Identifier (UDI):	(01)20385480422141 (11) 2 5 0 7 2 8 (17) 2 8 0 1 2 8 (10) 0 3 2 5 2 0 9 3 0 9	

MacBrosne
 Quality Control Manager

8/28/25
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454