



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	42214	
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:	5,040	
Lot No.	0325307249	
Mfg. Date:	2025-11-03	
Expiration Date:	2027-11-03	
Unique Device Identifier (UDI):	(01)20385480422141 (11)251103 (17)271103 (10)0325307249	

Alma Brown
 Quality Control Manager

11/19/25
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454