



CERTIFICATE OF COMPLIANCE Page 1/2

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:	NIPRO DIAGNOSTICS INC.	
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE, PACKAGED	
Catalog Number:	47940	
Nova Biomedical P/N	47940	
Target Range (mg/dL)	SD (mg/dL) /CV (%)	
30-50	≤ 4 mg/dL	<u>PASS</u> / FAIL
51-110	≤ 6.0%	<u>PASS</u> / FAIL
111-150	≤ 5.0%	<u>PASS</u> / FAIL
151-250	≤ 5.0%	<u>PASS</u> / FAIL
251-400	≤ 5.0%	<u>PASS</u> / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/-12% of reference method ≥ 95%		<u>PASS</u> / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/-15% of reference method ≥ 98%		<u>PASS</u> / FAIL
Qty:	304	
Lot No.	2125196309	
Mfg. Date:	2025-07-15	
Expiration Date:	2028-01-15	

Marc Broome 7/25/25
 Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

