

OI-922

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Rev. BS

Vialed and Packaged Test Strip Release

Test Strips

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, NOVA PRO GLUCOSE, PACKAGED 1800 COUNT	
Catalog Number:	53881	
Nova Biomedical P/N	53881	
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:	3,627	
Lot No.	1890226187	
Mfg. Date:	2026-07-06	
Expiration Date:	2028-07-06	
Unique Device Identifier (UDI):	(01)20385480538811 (11)260706 (17)280706 (10)1890226187	

Marc Browne
Quality Control Manager

8/3/26
Date

Nova Biomedical Corporation

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