

OI-922

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Rev. BG

Vialed and Packaged Test Strip Release

Test Strips

nova
biomedical

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)	Mean MPE (%)	CV (%)	
60-75	≤ 15	≤ 6.5	PASS / FAIL
120-160	≤ 15	≤ 5.5	PASS / FAIL
250-290	≤ 15	≤ 5.0	PASS / FAIL
380-420	≤ 15	≤ 5.0	PASS / FAIL
500-540	≤ 15	≤ 5.0	PASS / FAIL
Combined MPE (%)	≤ 10%		PASS / FAIL
Qty:	304		
Lot No.	2122172309		
Mfg. Date:	2022-06-21		
Expiration Date:	2024-12-31		

Quality Control Manager

Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454

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ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE
Catalog Number:	47940
Nova Biomedical P/N	47940
Lot No.	2122 172309

(Spiked whole blood) Target Range:60-75

Mean (mg/dL) N=72

CV%

YSI (reference, mg/dL)

Mean MPE%