

OI-922

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Rev. BH

Vialed and Packaged Test Strip Release

Test Strips

*nova*  
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**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.	2122279309
Mfg. Date:	2022.10.06
Expiration Date:	2025.04.30

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.	2122279309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤6.5		≤15
67	4.0	71.0	5.8

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.5		≤15
146	3.1	154.8	5.7

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
267	3.0	284.5	6.1

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
384	3.5	403.3	4.9

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
491	2.9	510.3	3.9

Quality Control Manager

Date

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