

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:	303
Lot No.	2123130309
Mfg. Date:	2023.05.08
Expiration Date:	2025.11.30

*Marc Bue*  
Quality Control Manager

5/23/2023  
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.	2123130309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤6.5		≤15
64	5.5	67.9	6.8

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.5		≤15
152	2.9	150.8	2.6

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
284	3.3	281.3	2.7

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
407	3.0	414.0	2.6

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
518	3.4	516.5	2.7

*March Brune*  
Quality Control Manager

*5/23/2023*  
Date

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