

OI-922

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Rev. BH

Vialed and Packaged Test Strip Release

Test Strips

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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.	2122314309
Mfg. Date:	2022.11.10
Expiration Date:	2025.05.31

Marc Brune
Quality Control Manager

11/15/2022
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.	2122314309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤6.5		≤15
65	3.5	66.2	3.0

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.5		≤15
154	4.2	155.3	3.3

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
276	3.6	285.8	4.2

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
407	2.9	413.8	2.6

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
492	3.1	512.5	4.1

Mary Browne
Quality Control Manager

11/15/2022
Date

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