

OI-922

Page 55 of 66

Rev. BH

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.	2123214309
Mfg. Date:	2023 - 07 - 31
Expiration Date:	2026 - 02 - 28

Marc Brosme
Quality Control Manager

8/4/2023
Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454

OI-922 Page 56 of 66 Rev. BH Vial and Packaged Test Strip Release Test Strips

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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.	2123214 309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤6.5		≤15
74	4.9	71.9	4.9

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.5		≤15
165	3.1	153.0	8.1

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
283	3.3	262.5	7.9

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
416	3.7	402.0	4.4

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
530	3.4	527.8	2.8

Quality Control Manager

Date

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