

OI 922 Page 52 of 62 Rev. AY Vial 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 CFR 21- Part 820, ISO 13485:2012, 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.	2118354309
Mfg. Date:	2018/12/19
Expiration Date:	2021/06

Maureen
Quality Control Manager

1/14/19
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.	2118354309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤6.5		≤15
69	4.2	71.6	4.0

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.5		≤15
159	3.3	158.3	2.6

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
285	2.9	277.8	3.2

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
426	3.2	417.0	3.1

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
524	3.2	514.8	3.0

Mark Brown
Quality Control Manager

1/14/19
Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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