

OI 922

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Rev. BA

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 13485:2012 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

Customer:	NIPRODIAGNOSTICS 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:	5,472
Lot No.	2119248309
Mfg. Date:	2019.09.04
Expiration Date:	2022.03.31


Quality Control Manager

9/25/19
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.	2119248309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
62	≤6.5 5.5	69.6	≤15 10.9

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
121	≤5.5 4.9	136.8	≤15 11.3

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
269	≤5.0 3.4	288.8	≤15 6.8

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
365	≤5.0 4.0	393.8	≤15 7.7

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
488	≤5.0 3.8	532.0	≤15 8.7

Quality Control Manager

Date

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