

OI-922 Page 53 of 63 Rev. BE Vial and Packaged Test Strip Release Test Strips



ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE
Catalog Number:	48880
Nova Biomedical P/N	48880
Lot No.	2122018309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤6.5		≤15
72	6.4	73.8	5.5

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.5		≤15
157	5.4	145.5	8.5

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
278	3.6	263.5	5.7

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
415	3.2	407.8	2.9

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
	≤5.0		≤15
512	3.1	504.0	2.8

Quality Control Manager

Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454

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Rev. BE

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 13485:2012 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:	48880
Nova Biomedical P/N	48880
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:	105
Lot No.	2122018309
Mfg. Date:	2022/01/18
Expiration Date:	2024/07/31

Mark Browne
Quality Control Manager

1/24/2022
Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454