

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:	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:	107
Lot No.	2123044309
Mfg. Date:	2023.07.13
Expiration Date:	2025.08.31

MacBorne 2/15/2023
Quality Control Manager Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454

OI-922

Page 56 of 66

Rev. BH

Vialed and Packaged Test Strip Release

Test Strips

nova
biomedical

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.	2123044309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤6.5		≤15
62	5.0	65.0	5.7

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.5		≤15
146	3.6	154.0	5.5

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
263	3.0	278.5	5.5

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
378	3.9	409.0	7.5

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
	≤5.0		≤15
478	3.1	520.3	8.8

Quality Control Manager

Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454

Released Confidential