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:	106
Lot No.	2121309309
Mfg. Date:	2021.11.05
Expiration Date:	2024.05.31

Marc Browne 11/10/21

Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

Released Confidential

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.	[illegible]

69 5.6 74.1 7.6

152 3.6 144.3 5.5

281 3.7 271.0 4.4

Range:380-420	
reference, mg/dL))	Mean MPE%
	≦15
404.6	2.8

Range:500-540	
reference, mg/dL))	Mean MPE%
	≦15
527.38	3.7

[illegible]/[illegible]

te

ct Street Waltham, MA 02454

	(Spiked whole blood)	Target
Mean (mg/dL) N=72	CV%	YSI (
	≦5.0	
406	3.4	

	(Spiked whole blood)	Target
Mean (mg/dL) N=72	CV%	YSI (
	≦5.0	
526	4.7	

[illegible]

Quality Control Manager Da

Nova Biomedical Corporation 200 Prospe