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: ESL 4/25/23	~~105~~ 107
Lot No.	2123107309
Mfg. Date:	2023.04.17
Expiration Date:	2025.10.31

Marc Browne 4/25/2023

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.	2123107309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
69	3.8 ≦6.5	71.0	3.6 ≦15

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
159	4.2 ≦5.5	160.0	3.3 ≦15

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
287	3.4 ≦5.0	284.3	2.7 ≦15

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
397	3.7 ≦5.0	400.3	3.1 ≦15

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL))	Mean MPE%
510	2.9 ≦5.0	517.5	2.4 ≦15

Quality Control Manager Date 4/25/23

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

Released Confidential