

OI-922

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Rev. BH

Vialed and Packaged Test Strip Release

Test Strips

nova
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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:	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:	304
Lot No.	2122321309
Mfg. Date:	2022.11.17
Expiration Date:	2025.05.31

Marc Brosne
Quality Control Manager

11/28/2022
Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454

Released Confidential

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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.	2122321309

(Spiked whole blood) Target Range:60-75			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
73	3.6 ≤6.5	68.5	6.5 ≤15

(Spiked whole blood) Target Range:120-160			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
144	3.8 ≤5.5	135.3	6.8 ≤15

(Spiked whole blood) Target Range:250-290			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
276	3.4 ≤5.0	258.5	6.9 ≤15

(Spiked whole blood) Target Range:380-420			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
422	3.7 ≤5.0	400.5	5.7 ≤15

(Spiked whole blood) Target Range:500-540			
Mean (mg/dL) N=72	CV%	YSI (reference, mg/dL)	Mean MPE%
515	3.7 ≤5.0	512.0	2.9 ≤15

Mark Browne 11/28/2022
Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454