

OI-922

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Vialed and Packaged Test Strip Release

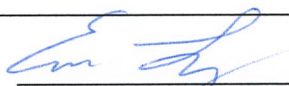
Test Strips

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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:	48880
Nova Biomedical P/N	48880
Target Range (mg/dL) SD (mg/dL) /CV (%)	
30-50 ≤ 4 mg/dL	PASS / FAIL
51-110 ≤ 6.0%	PASS / FAIL
111-150 ≤ 5.0%	PASS / FAIL
151-250 ≤ 5.0%	PASS / FAIL
251-400 ≤ 5.0%	PASS / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%	PASS / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%	PASS / FAIL
Qty:	104
Lot No.	2123297309
Mfg. Date:	2023.10.24
Expiration Date:	2026.04.30



Quality Control Manager

11/14/23

Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454

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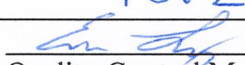
ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE
Catalog Number:	48880
Nova Biomedical P/N	48880
Lot No.	2123297309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤ 4	YSI (reference, mg/dL)
39	2.4	37.4
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤ 6.0	YSI (reference, mg/dL)
112	4.7	109.3
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
149	2.6	146.0
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
243	4.5	235.0
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
393	3.2	398.8

Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method $\geq 95\%$	Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method $\geq 98\%$
98.2%	100.0%


Quality Control Manager
Nova Biomedical Corporation

11/14/23
Date
200 Prospect Street Waltham, MA 02454