

OI-922

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Rev. BL

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) 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:	103
Lot No.	2124278309
Mfg. Date:	2024.10.04
Expiration Date:	2027.04.30

Marc Broome
Quality Control Manager

10/7/24
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.	2124278309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤ 4	YSI (reference, mg/dL)
44	2.9	48.8
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤ 6.0	YSI (reference, mg/dL)
102	3.7	97.2
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
145	3.8	140
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
241	3.1	235.3
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
395	3.7	392.0

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 $\geq 98\%$
98.6%	99.8%

Quality Control Manager
Nova Biomedical Corporation

Date

10/2/24
200 Prospect Street Waltham, MA 02454