

OI-922

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Rev. BJ

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:	47940
Nova Biomedical P/N	47940
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:	304
Lot No.	2123347309
Mfg. Date:	2023.12.13
Expiration Date:	2026.06.30


Quality Control Manager

1/4/24
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:	47940
Nova Biomedical P/N	47940
Lot No.	2123347309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤ 4	YSI (reference, mg/dL)
46	3.1	49.7
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤ 6.0	YSI (reference, mg/dL)
99	3.9	100.5
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
137	3.0	138.8
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
229	3.1	233.5
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
359	3.2	368.8

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 $\geq 98\%$
99.8 %	100.0 %

Am Long
Quality Control Manager
Nova Biomedical Corporation

1/4/24
Date
200 Prospect Street Waltham, MA 02454