

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:	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.	2124015309
Mfg. Date:	2024.01.15
Expiration Date:	2026.07.31


Quality Control Manager


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.	2124015309

(Spiked whole blood) Target Range:30-50

Mean (mg/dL) N=100

SD (mg/dL) ≤ 4

YSI (reference, mg/dL))

36

2.6

42.8

(Spiked whole blood) Target Range:51-110

Mean (mg/dL) N=100

CV% ≤ 6.0

YSI (reference, mg/dL))

103

4.8

101.9

(Spiked whole blood) Target Range:111-150

Mean (mg/dL) N=100

CV% ≤ 5.0

YSI (reference, mg/dL))

133

4.5

135.0

(Spiked whole blood) Target Range:151-250

Mean (mg/dL) N=100

CV% ≤ 5.0

YSI (reference, mg/dL))

224

3.6

226.0

(Spiked whole blood) Target Range:251-400

Mean (mg/dL) N=100

CV% ≤ 5.0

YSI (reference, mg/dL))

361

3.4

361.3

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 $\geq 98\%$

99.2 %

99.8 %

Quality Control Manager

Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454