

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.	2124071309
Mfg. Date:	2024-03-11
Expiration Date:	2026-09-30

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.	2124071309

**(Spiked whole blood) Target Range:30-50**

Mean (mg/dL) N=100	SD (mg/dL) $\leq 4$	YSI (reference, mg/dL)
46	2.6	48.8

**(Spiked whole blood) Target Range:51-110**

Mean (mg/dL) N=100	CV% $\leq 6.0$	YSI (reference, mg/dL)
93	4.9	90.6

**(Spiked whole blood) Target Range:111-150**

Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
137	3.1	137.5

**(Spiked whole blood) Target Range:151-250**

Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
227	3.5	229.5

**(Spiked whole blood) Target Range:251-400**

Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
359	3.1	370.8

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

98.8%

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

99.8%

Quality Control Manager  
Nova Biomedical Corporation

Date  
3/14/24  
200 Prospect Street Waltham, MA 02454

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