

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	<u>PASS</u> / FAIL
51-110                    ≤ 6.0%	<u>PASS</u> / FAIL
111-150                  ≤ 5.0%	<u>PASS</u> / FAIL
151-250                  ≤ 5.0%	<u>PASS</u> / FAIL
251-400                  ≤ 5.0%	<u>PASS</u> / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%	<u>PASS</u> / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%	<u>PASS</u> / FAIL
Qty:	304
Lot No.	2124037309
Mfg. Date:	2024.02.06
Expiration Date:	2026.07.31

Manbowe  
Quality Control Manager

2/15/2024  
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.	2124037309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) $\leq 4$	YSI (reference, mg/dL)
39	2.7	39.6
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% $\leq 6.0$	YSI (reference, mg/dL)
101	3.3	97.1
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
140	3.3	136.3
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
234	3.2	233.5
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
364	2.9	368.3

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 $\geq 98\%$
99.6%	100.0%

Quality Control Manager  
Nova Biomedical Corporation

Date

2/15/2024  
200 Prospect Street Waltham, MA 02454

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