

*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.	2125100309	
Mfg. Date:	2025.04.10	
Expiration Date:	2027.10.10	

Marc Browne 4/15/25  
Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

OI-922

Page 57 of 67

Rev. BN

Vialed and Packaged Test Strip Release

Test Strips

*nova*  
biomedical

**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.	2125100309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) $\leq 4$	YSI (reference, mg/dL)
44	2.4	45.4
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% $\leq 6.0$	YSI (reference, mg/dL)
101	4.5	100.6
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
133	3.5	134.0
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
218	2.4	218.8
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
343	2.5	346.5

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 $\geq 98\%$
100.0%	100.0%

*Mauro Broz*  
Quality Control Manager  
Nova Biomedical Corporation

4/15/25  
Date  
200 Prospect Street Waltham, MA 02454