



**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.	2125101309	
Mfg. Date:	2025.04.11	
Expiration Date:	2027.10.11.	

Marc Brune  
Quality Control Manager

4/15/25  
Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

OI-922 Page 57 of 67 Rev. BN Vial 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:	48880
Nova Biomedical P/N	48880
Lot No.	2125101309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) $\leq 4$	YSI (reference, mg/dL)
42	2.5	42-0
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% $\leq 6.0$	YSI (reference, mg/dL)
102	4.6	103.8
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
140	3.5	144-0
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
233	2.9	242-0
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% $\leq 5.0$	YSI (reference, mg/dL)
370	3.0	392-3

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 $\geq 98\%$
99.4	100.0

*Marc Browne*  
Quality Control Manager  
Nova Biomedical Corporation

*9/15/25*  
Date  
200 Prospect Street Waltham, MA 02454