

*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	<del>PASS</del> FAIL
51-110	≤ 6.0%	<del>PASS</del> FAIL
111-150	≤ 5.0%	<del>PASS</del> FAIL
151-250	≤ 5.0%	<del>PASS</del> FAIL
251-400	≤ 5.0%	<del>PASS</del> FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/-12% of reference method ≥ 95%		<del>PASS</del> FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/-15% of reference method ≥ 98%		<del>PASS</del> FAIL
Qty:	304	
Lot No.	2124248309	
Mfg. Date:	2024.09.04	
Expiration Date:	2027.03.31	

Mary Borne      9/11/2024  
 Quality Control Manager      Date

Nova Biomedical Corporation      200 Prospect Street      Waltham, MA 02454



**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.	2124248309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤4	YSI (reference, mg/dL)
46	2.6	44.2
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤6.0	YSI (reference, mg/dL)
100	4.7	94.7
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
132	4.8	135.0
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
217	3.0	222.0
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
344	4.0	345.8

Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%	Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%
97.4%	99.4%

Marc Broome 9/11/24  
 Quality Control Manager Date  
 Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454