



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	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:	304	
Lot No.	2124282309	
Mfg. Date:	2024.10.08	
Expiration Date:	2027.04.30	

MacBrowne
 Quality Control Manager

10/11/24
 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.	2124282309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤4	YSI (reference, mg/dL)
42	2.3	42.2
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤6.0	YSI (reference, mg/dL)
106	3.3	104.8
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
140	2.8	140.5
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
227	2.0	226.5
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
351	2.7	354.0

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%
99.8%	99.8%

Mas Broome
Quality Control Manager
Nova Biomedical Corporation

10/11/24
Date

200 Prospect Street Waltham, MA 02454