



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:	103	
Lot No.	2124250309	
Mfg. Date:	2024.09.06	
Expiration Date:	2027.03.31	

Marc Browne
 Quality Control Manager

9/11/24
 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:	48880
Nova Biomedical P/N	48880
Lot No.	2124250309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤4	YSI (reference, mg/dL)
38	2.9	39.3
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤6.0	YSI (reference, mg/dL)
107	4.7	105.3
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
136	5.5	139.5
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
240	3.1	245.8
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
387	3.7	391.0

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%
99.4%	99.6%

Maria Byrne
 Quality Control Manager
 Nova Biomedical Corporation

9/11/24
 Date
 200 Prospect Street Waltham, MA 02454