



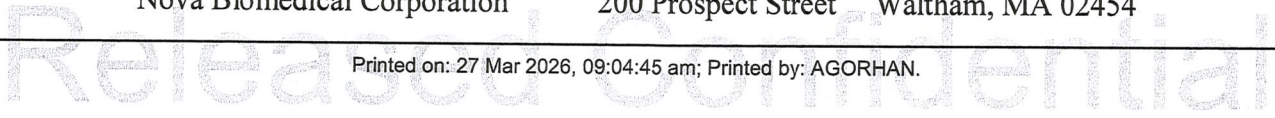
CERTIFICATE OF COMPLIANCE Page 1/2

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.	2126069309	
Mfg. Date:	2026-03-10	
Expiration Date:	2028-09-10	

Maureen 3/27/26
 Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454





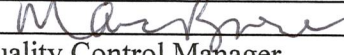
ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE
Catalog Number:	48880
Nova Biomedical P/N	48880
Lot No.	2126069309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤4	YSI (reference, mg/dL)
42	2.4	44.5
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤6.0	YSI (reference, mg/dL)
104	4.9	99.8
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
139	4.3	134.8
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
226	3.2	226.8
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
354	3.3	355.0

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%
97.4%	99.0%


 Quality Control Manager Date 3/27/26
 Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454