



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.

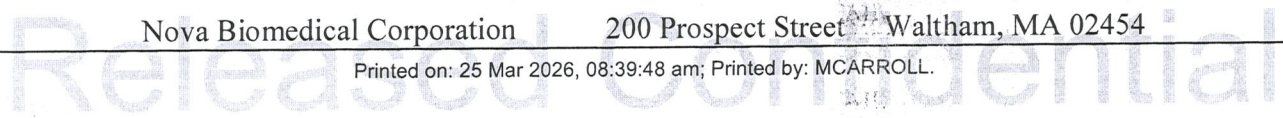
The enzyme levels meet the following specifications:

- iii) Test Inspection Item: Glucose + Enzymes (oxidized form) \geq 1.0 IU per strip
- iv) Test Inspection Item: Ferrocyanide \geq 20 μ g per strip

Customer:	NIPRO - ODATE FACTORY	
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE, 25 COUNT, COLUMN (RAW MATERIAL)	
Catalog Number:	59363	
Nova Biomedical P/N	59363	
Target Range (mg/dL)	SD(mg/dL) /CV (%)	
30-50	\leq 4 mg/dL	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
51-110	\leq 6.0%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
111-150	\leq 5.0%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
151-250	\leq 5.0%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
251-400	\leq 5.0%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/-12% of reference method \geq 95%		<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method \geq 98%		<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL
Qty:	23,025	
Lot No.	2126070309	
Mfg. Date:	2026-03-11	
Expiration Date:	2028-09-11	

Maur Bone
 Quality Control Manager

3/25/26
 Date





ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO - ODATE FACTORY
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE, 25 COUNT, COLUMN (RAW MATERIAL)
Catalog Number:	59363
Nova Biomedical P/N	59363
Lot No.	212070309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD(mg/dL) ≤4	YSI (reference, mg/dL)
45	2.2	46.4
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤6.0	YSI (reference, mg/dL)
103	3.9	102.0
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
135	3.6	138.3
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
221	2.9	226.5
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
349	3.2	351.3

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%
100.0%	100.0%

Maura Broome
 Quality Control Manager
 Nova Biomedical Corporation

3/25/26
 Date
 200 Prospect Street Waltham, MA 02454