



**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  $\mu$ 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	<u>PASS</u> / FAIL
51-110	$\leq$ 6.0%	<u>PASS</u> / FAIL
111-150	$\leq$ 5.0%	<u>PASS</u> / FAIL
151-250	$\leq$ 5.0%	<u>PASS</u> / FAIL
251-400	$\leq$ 5.0%	<u>PASS</u> / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method $\geq$ 95%		<u>PASS</u> / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method $\geq$ 98%		<u>PASS</u> / FAIL
Qty:	<del>22,438</del> 22,463	
Lot No.	2124128309	
Mfg. Date:	2024-05-07	
Expiration Date:	2026-11-30	

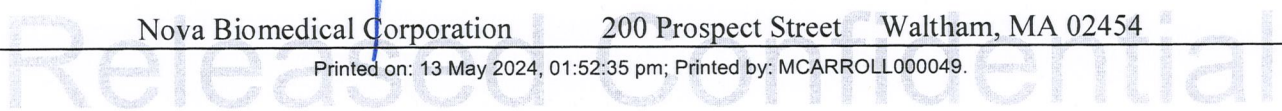
Quality Control Manager

Date

5/24/24

MFC 5/14/24

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454





**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.	2124128309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD(mg/dL) ≤4	YSI (reference, mg/dL)
43	2.0	43.3
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤6.0	YSI (reference, mg/dL)
105	4.2	103.5
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
137	3.6	138.5
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
226	3.2	228.5
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤5.0	YSI (reference, mg/dL)
344	2.8	352.8

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%
99.6%	100.0%

Quality Control Manager  
 Nova Biomedical Corporation

Date 5/19/24  
 200 Prospect Street Waltham, MA 02454