

OI-922

Page 53 of 66

Rev. BJ

Vialed and Packaged Test Strip Release

Test Strips



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) ≥ 1.0 IU per strip
- iv) Test Inspection Item: Ferrocyanide ≥ 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 ≤ 4 mg/dL	PASS / FAIL
51-110 $\leq 6.0\%$	PASS / FAIL
111-150 $\leq 5.0\%$	PASS / FAIL
151-250 $\leq 5.0\%$	PASS / FAIL
251-400 $\leq 5.0\%$	PASS / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method $\geq 95\%$	PASS / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method $\geq 98\%$	PASS / FAIL
Qty:	22,823
Lot No.	2123296309
Mfg. Date:	2023.10.23
Expiration Date:	2026.04.30

Quality Control Manager

11/2/23
Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

Printed on: 02 Nov 2023, 11:05:21 am; Printed by: MCARROLL000049.

Released Confidential

OI-922 Page 54 of 66 Rev. BJ Vialled and Packaged Test Strip Release Test Strips

nova
biomedical

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.	2123296309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD(mg/dL) ≤ 4	YSI (reference, mg/dL)
47	2.1	43.8
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤ 6.0	YSI (reference, mg/dL)
108	3.5	100.5
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
147	3.2	138.0
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
243	2.8	238.3
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
366	3.2	367.3

Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method $\geq 95\%$	Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method $\geq 98\%$
96.8 %	99.2 %

Quality Control Manager
Nova Biomedical Corporation

Date 11/2/2023
200 Prospect Street Waltham, MA 02454