

OI-922

Page 55 of 66

Rev. BJ

Vialed and Packaged Test Strip Release

Test Strips

nova
biomedical

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:	47940
Nova Biomedical P/N	47940
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:	304
Lot No.	2124074309
Mfg. Date:	2024-03-14
Expiration Date:	2026-09-30

Quality Control Manager

Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454

OI-922 Page 56 of 66 Rev. BJ Vial and Packaged Test Strip Release Test Strips

nova
biomedical

ADDENDUM TO CERTIFICATE OF COMPLIANCE Page 2/2

RELEASE TEST RESULTS

Customer:	NIPRO DIAGNOSTICS INC.
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE
Catalog Number:	47940
Nova Biomedical P/N	47940
Lot No.	2124074309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≤ 4	YSI (reference, mg/dL)
40	2.0	43.5
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≤ 6.0	YSI (reference, mg/dL)
93	5.0	95.1
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
126	4.6	132.3
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
226	3.4	231.5
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≤ 5.0	YSI (reference, mg/dL)
357	3.3	377.5

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 $\geq 98\%$
98.6%	99.8%

Quality Control Manager
Nova Biomedical Corporation

Date 3/14/24
200 Prospect Street Waltham, MA 02454

Released Confidential