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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.	2124073309
Mfg. Date:	2024-03-13
Expiration Date:	2026-09-30

Quality Control Manager Date 3/14/24

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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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.	2124073309

(Spiked whole blood) Target Range:30-50		
Mean (mg/dL) N=100	SD (mg/dL) ≦4	YSI (reference, mg/dL))
41	2.4	44.7
(Spiked whole blood) Target Range:51-110		
Mean (mg/dL) N=100	CV% ≦6.0	YSI (reference, mg/dL))
97	5.3	100.3
(Spiked whole blood) Target Range:111-150		
Mean (mg/dL) N=100	CV% ≦5.0	YSI (reference, mg/dL))
136	4.0	142.3
(Spiked whole blood) Target Range:151-250		
Mean (mg/dL) N=100	CV% ≦5.0	YSI (reference, mg/dL))
237	2.8	244.3
(Spiked whole blood) Target Range:251-400		
Mean (mg/dL) N=100	CV% ≦5.0	YSI (reference, mg/dL))
360	2.7	380.8

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%
98.0 %	99.6 %

Quality Control Manager Date 3/14/24
Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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