

OI-922

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Rev. BJ

Vialed and Packaged Test Strip Release

Test Strips

nova
biomedical

CERTIFICATE OF COMPLIANCE

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:	NIA
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:	42214
Nova Biomedical P/N	55890
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:	1,050
Lot No.	0324008249
Mfg. Date:	2024-01-08
Expiration Date:	2026-01-08
Unique Device Identifier (UDI):	(01)20385480422141 (11) 240108 (17) 260108 (10) 0324008249

MacBroom
Quality Control Manager

1/12/24
Date

Nova Biomedical Corporation

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