

OI-922 Page 36 of 66 Rev. BJ Vial and Packaged Test Strip Release Test Strips



## 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 A GLUCOSE INT'L, PACKAGED 100 COUNT	
Catalog Number:	59352	
Nova Biomedical P/N	59352	
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:	100	
Lot No.	1122173309	
Mfg. Date:	2022-06-22	
Expiration Date:	2024-12-22	
Unique Device Identifier (UDI):	(01)20385480593520 (11)220622 (17)241222 (10)1122173309	

Marc Swome 2/8/24  
Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454