

OI-922

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Rev. BH

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:	N/A		
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT		
Catalog Number:	42214		
Nova Biomedical P/N	51493		
Target Range (mg/dL)	Mean MPE (%)	CV (%)	
60-75	≤ 15	≤ 6.5	PASS / FAIL
120-160	≤ 15	≤ 5.5	PASS / FAIL
250-290	≤ 15	≤ 5.0	PASS / FAIL
380-420	≤ 15	≤ 5.0	PASS / FAIL
500-540	≤ 15	≤ 5.0	PASS / FAIL
Combined MPE (%)	≤ 10%		PASS / FAIL
Qty:	6,720		
Lot No.	0322335309		
Mfg. Date:	2022-12-01		
Expiration Date:	2025-06-01		
Unique Device Identifier (UDI):	(01)20385480422141 (11)221201 (17)250601 (10)0322335309		

Marc Broome
Quality Control Manager

12/20/2022
Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454