

OI-922

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Rev. BH

Vialed 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:	N/A
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:	42214
Nova Biomedical P/N	42214
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:	3,842
Lot No.	0323228249
Mfg. Date:	2023-08-16
Expiration Date:	2025-08-16
Unique Device Identifier (UDI):	(01)20385480422141 (11) 230816 (17) 250816 (10) 0323228249

Quality Control Manager

10/13/23
Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454