

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:	LIFESCAN
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT
Lifescan Purchase Order No.:	442957
Catalog Number:	42214
Nova Biomedical P/N	54311
One Touch P/N	02307501
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:	30,240
Lot No.	0322356309
Date of Mfg. (DOM):	2022/12/22 (YYYY/MM/DD)
Expiration Date:	2025/06 (YYYY/MM)
Unique Device Identifier (UDI):	(01)20385480422141 (11)221222 (17)250622 (10)0322356309

Marc B...
Quality Control Manager

1/11/2023
Date

Nova Biomedical Corporation

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