

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:	LIFESCAN
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT
Lifescan Purchase Order No.:	440902
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:	15,120
Lot No.	0322335309
Date of Mfg. (DOM):	2022 / 12 / 01 (YYYY/MM/DD)
Expiration Date:	2025 / 06 (YYYY/MM)
Unique Device Identifier (UDI):	(01)20385480422141 (11)221201 (17)250601 (10)0322335309

Marc Broome
Quality Control Manager

12/13/2022
Date

Nova Biomedical Corporation

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