

OI 922

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Rev. AY

Vialed and Packaged Test Strip Release

Test Strips



CERTIFICATE OF COMPLIANCE

This product has been manufactured in compliance with CFR 21- Part 820, ISO 13485:2012, and meets Nova Biomedical product specifications.

Customer:	LIFESCAN
Description:	TEST STRIPS, LIFESCAN ONETOUCH STATSTRIP GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT
Lifescan Purchase Order No.:	017010D533942
Catalog Number:	N/A
Nova Biomedical P/N	53995
One Touch P/N	02334001
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:	3024
Lot No.	0319073309
Date of Mfg. (DOM):	2019 / 03 / 01 (YYYY/MM/DD)
Expiration Date:	2021 / 09 (YYYY/MM)

MacBorne
Quality Control Manager

3/28/19
Date

Nova Biomedical Corporation

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