

OI-922 Page 40 of 66 Rev. BJ Vial 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.:	474118
Catalog Number:	42214
Nova Biomedical P/N	54311
One Touch P/N	02307501
Target Range (mg/dL) SD(mg/dL) /CV (%)	
30-50 ≤ 4 mg/dL	PASS / FAIL
51-110 ≤ 6.0%	PASS / FAIL
111-150 ≤ 5.0%	PASS / FAIL
151-250 ≤ 5.0%	PASS / FAIL
251-400 ≤ 5.0%	PASS / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%	PASS / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%	PASS / FAIL
Qty:	27,216
Lot No.	0324057309
Date of Mfg. (DOM):	2024/02/26 (YYYY/MM/DD)
Expiration Date:	2026/08 (YYYY/MM)
Unique Device Identifier (UDI):	(01)20385480422141 (11) 240226 (17) 260826 (10) 0324057309

Quality Control Manager

Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454

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