



**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.:	477069
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:	9,072
Lot No.	0324120309
Date of Mfg. (DOM):	2024 / 04 / 29 (YYYY/MM/DD)
Expiration Date:	2026 / 10 (YYYY/MM)
Unique Device Identifier (UDI):	(01)20385480422141 (11) <u>24 0429</u> (17) <u>26 1029</u> (10) <u>0324120309</u>

*Mar Browne*  
Quality Control Manager

*5/30/24*  
Date