



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.:	640791	
Catalog Number:	42214	
Nova Biomedical P/N	54515	
One Touch P/N	02315302	
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:	21,168	
Lot No.	0324115249	
Date of Mfg. (DOM):	2024/04/24 (YYYY/MM/DD)	
Expiration Date:	2026/04/24 (YYYY/MM/DD)	
Unique Device Identifier (UDI):	(01)20385480422141 (11)240424 (17)260424 (10)0324115249	


 Quality Control Manager

5/20/24
 Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454

