



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.

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|---|--|-------------|
| Customer: | LIFESCAN | |
| Description: | TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT | |
| Lifescan Purchase Order No.: | 504358 | |
| 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: | 33,264 | |
| Lot No. | 0325275309 | |
| Date of Mfg. (DOM): | 2025 / 10 / 02 (YYYY/MM/DD) | |
| Expiration Date: | 2028 / 04 (YYYY/MM) | |
| Unique Device Identifier (UDI): | (01)20385480422141 (11) <u>251002</u> (17) <u>280402</u> (10) <u>0325275309</u> | |

Marc Broome
 Quality Control Manager

4/3 11/14/25
 NB Date
 11/14/25

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454

