



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 KETONE, PACKAGED 18 BOXES OF 50 COUNT | | | | | | | | | | | | | | | | |
| Lifescan Purchase Order No.: | 509045 | | | | | | | | | | | | | | | | |
| Catalog Number: | 46951 | | | | | | | | | | | | | | | | |
| Nova Biomedical P/N | 55932 | | | | | | | | | | | | | | | | |
| One Touch P/N | 02309002 | | | | | | | | | | | | | | | | |
| <table border="1"> <thead> <tr> <th>Target Range</th> <th>MPE</th> <th>SD/CV (%)</th> <th></th> </tr> </thead> <tbody> <tr> <td>0.1-0.8 mmol/L</td> <td>+/- 0.3 mmol/L</td> <td>≤ 0.1 mmol/L</td> <td>PASS / FAIL</td> </tr> <tr> <td>1.5-2.5 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td>PASS / FAIL</td> </tr> <tr> <td>3.5-5.0 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td>PASS / FAIL</td> </tr> </tbody> </table> | Target Range | MPE | SD/CV (%) | | 0.1-0.8 mmol/L | +/- 0.3 mmol/L | ≤ 0.1 mmol/L | PASS / FAIL | 1.5-2.5 mmol/L | +/- 20% | ≤ 10% | PASS / FAIL | 3.5-5.0 mmol/L | +/- 20% | ≤ 10% | PASS / FAIL | |
| Target Range | MPE | SD/CV (%) | | | | | | | | | | | | | | | |
| 0.1-0.8 mmol/L | +/- 0.3 mmol/L | ≤ 0.1 mmol/L | PASS / FAIL | | | | | | | | | | | | | | |
| 1.5-2.5 mmol/L | +/- 20% | ≤ 10% | PASS / FAIL | | | | | | | | | | | | | | |
| 3.5-5.0 mmol/L | +/- 20% | ≤ 10% | PASS / FAIL | | | | | | | | | | | | | | |
| Qty: | 10,080 | | | | | | | | | | | | | | | | |
| Lot No. | 2226005249 | | | | | | | | | | | | | | | | |
| Date of Mfg. (DOM): | 2026 / 01 / 05 (YYYY/MM/DD) | | | | | | | | | | | | | | | | |
| Expiration Date: | 2028 / 01 / 05 (YYYY/MM/DD) | | | | | | | | | | | | | | | | |
| Unique Device Identifier (UDI): | (01)20385480469511 (11)260105 (17)280105 (10)2226005249 | | | | | | | | | | | | | | | | |

Quality Control Manager

Date

Nova Biomedical Corporation

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