

OI-922 Page 60 of 66 Rev. BH 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: | N/A | | | | | | | | | | | | | | | |
|--|--|--------------|-----------|----------------|----------------|--------------|----------------|---------|-------|----------------|---------|-------|--|-------------|-------------|-------------|
| Description: | TEST STRIPS, STATSTRIP™ KETONE, PACKAGED 50 CT | | | | | | | | | | | | | | | |
| Catalog Number: | 46951 | | | | | | | | | | | | | | | |
| Nova Biomedical P/N | 46951 | | | | | | | | | | | | | | | |
| <table border="1"><thead><tr><th>Target Range</th><th>MPE</th><th>SD/CV (%)</th></tr></thead><tbody><tr><td>0.1-0.8 mmol/L</td><td>+/- 0.3 mmol/L</td><td>≤ 0.3 mmol/L</td></tr><tr><td>1.5-2.5 mmol/L</td><td>+/- 20%</td><td>≤ 15%</td></tr><tr><td>3.5-5.0 mmol/L</td><td>+/- 20%</td><td>≤ 15%</td></tr></tbody></table> | Target Range | MPE | SD/CV (%) | 0.1-0.8 mmol/L | +/- 0.3 mmol/L | ≤ 0.3 mmol/L | 1.5-2.5 mmol/L | +/- 20% | ≤ 15% | 3.5-5.0 mmol/L | +/- 20% | ≤ 15% | <table border="1"><tbody><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr></tbody></table> | PASS / FAIL | PASS / FAIL | PASS / FAIL |
| Target Range | MPE | SD/CV (%) | | | | | | | | | | | | | | |
| 0.1-0.8 mmol/L | +/- 0.3 mmol/L | ≤ 0.3 mmol/L | | | | | | | | | | | | | | |
| 1.5-2.5 mmol/L | +/- 20% | ≤ 15% | | | | | | | | | | | | | | |
| 3.5-5.0 mmol/L | +/- 20% | ≤ 15% | | | | | | | | | | | | | | |
| PASS / FAIL | | | | | | | | | | | | | | | | |
| PASS / FAIL | | | | | | | | | | | | | | | | |
| PASS / FAIL | | | | | | | | | | | | | | | | |
| Qty: | 4,583 | | | | | | | | | | | | | | | |
| Lot No. | 2223128249 | | | | | | | | | | | | | | | |
| Mfg. Date: | 2023-05-08 | | | | | | | | | | | | | | | |
| Expiration Date: | 2025-05-08 | | | | | | | | | | | | | | | |
| Unique Device Identifier (UDI): | (01)20385480 469511 (11) 230508 (17) 250508 (10) 2223128249 | | | | | | | | | | | | | | | |

Marc Broome 5/22/2023
Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454