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Rev. BJ

Vialed 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: | NIN |
|--|--------------------------------|
| Description: | TEST STRIPS, STATSTRIP TM |
| | GLUCOSE, PACKAGED 1800 COUNT |
| | GEOCOSE, I MORNIGED 1000 COCKI |
| Catalaa Numban | 42214 |
| Catalog Number: | |
| Nova Biomedical P/N | 55890 |
| 11074 Diomodical 1711 | 55010 |
| Target Range (mg/dL) SD(mg/dL) /CV (%) | |
| | |
| | |
| $30-50 		 \leq 4 \text{ mg/dL}$ | (PASS// FAIL |
| | |
| $51-110 \leq 6.0\%$ | (PASS)// FAIL |
| 111 150 - 5 00/ | |
| $111-150 \leq 5.0\%$ | PASS/ FAIL |
| 151-250 ≤ 5.0% | TAGE / PAY |
| 151-250 \(\leq 5.076\) | PASS / FAIL |
| 251 - 400 ≤ 5.0% | (PASS) / FAIL |
| 231 100 | PASS/ FAIL |
| Accuracy Criteria 1: Total within +/-12 mg/dL or | PASS FAIL |
| +/- 12% of reference method \geq 95% | TAILS 1, TAILS |
| _ | |
| Accuracy Criteria 2: Total within +/-15 mg/dL or +/- | (PAS\$ / FAIL |
| 15% of reference method ≥ 98% | |
| Qty: | 630 |
| | |
| Lot No. | 0323362249 |
| Mfg. Date: | 2023 - 12 - 28 |
| Mig. Date. | |
| Expiration Date: | 2025 -12-28 |
| • | |
| Unique Device Identifier (UDI): | (01)20385480422141 |
| | (11) 2 3 1 2 2 8 |
| | (17) 2 5 1 0 0 0 |
| | (11) 45 1428 |
| A-1 | (10) 0 3 2 3 3 6 2 2 4 4 |
| Mais mome | 1/5/2024 |
| Quality Control Manager | Date |

Nova Biomedical Corporation

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