

OI-922

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Rev. BJ

Vialed and Packaged Test Strip Release

Test Strips

nova
biomedical

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: | NIA | |
| Description: | TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT | |
| Catalog Number: | 42214 | |
| Nova Biomedical P/N | 51493 | |
| 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: | 2,520 | |
| Lot No. | 0823345309 | |
| Mfg. Date: | 2023-12-11 | |
| Expiration Date: | 2026-06-11 | |
| Unique Device Identifier (UDI): | (01)20385480422141 (11) 231211 (17) 260611 (10) 0323345309 | |

Mark Brouse
Quality Control Manager

12/20/23
Date

Nova Biomedical Corporation

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