

OI-922

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Rev. BN

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 CAPILLARY GLUCOSE ROW, PACKAGED 100 COUNT |
| Catalog Number: | 61500 |
| Nova Biomedical P/N | 61500 |
| Target Range (mg/dL) SD(mg/dL) /CV (%) | |
| 30-50 ≤ 4 mg/dL | <u>PASS</u> / FAIL |
| 51-110 ≤ 6.0% | <u>PASS</u> / FAIL |
| 111-150 ≤ 5.0% | <u>PASS</u> / FAIL |
| 151-250 ≤ 5.0% | <u>PASS</u> / FAIL |
| 251-400 ≤ 5.0% | <u>PASS</u> / FAIL |
| Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95% | <u>PASS</u> / FAIL |
| Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98% | <u>PASS</u> / FAIL |
| Qty: | 20,034 |
| Lot No. | 0325085309 |
| Mfg. Date: | 2025-03-26 |
| Expiration Date: | 2027-09-26 |
| Unique Device Identifier (UDI): | (01)20385480615000 (11) <u>250326</u> (17) <u>270926</u> (10) <u>0325085309</u> |

Maureen
Quality Control Manager

7/24/25
Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454