

Attachment 2



Certificate of Conformance & Analysis

Nova Biomedical certifies that the following Nova Max Product has been built and tested in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) and meets Nova Biomedical product specifications.

Description: Test Strip 100ct CA Nova Max
 Part Number: 43955
 BOM Rev.: C
 Lot Number: 1020223261
 Expiration Date: 2025-09-18
 Date of Manufacture: 2023-09-18
 UDI: (01)20385480 439552
 (11) 230918
 (17) 250918
 (10) 1020223261
 Quantity: 5,280
 Date of Release: 2023-10-02

| Release Test Results Summary | | | | | |
|----------------------------------------------------------------------------------------------|------------------|--------------|--------------------|---------------------|-----|
| Target Level (mg/dL) | YSI Mean (mg/dL) | Mean (mg/dL) | SD (mg/dL) /CV (%) | SD/CV Specification | P/F |
| 30-50 | 44.2 | 44 | 3.9 | ≤ 4 mg/dL | P |
| 51-110 | 71.4 | 69 | 4.9 | ≤6.0% | P |
| 111-150 | 137.0 | 135 | 4.2 | ≤5.0% | P |
| 151-250 | 241.5 | 232 | 4.4 | ≤5.0% | P |
| 251-400 | 392.8 | 391 | 3.8 | ≤5.0% | P |
| Accuracy Criteria 1: Total within +/-11.3 mg/dL or +/- 15% of reference method: <u>99.8%</u> | | | | Specification: ≥95% | P |
| Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 20% of reference method: <u>100.0%</u> | | | | Specification: ≥99% | P |

NOTE: Test data in table above taken from completed and approved Data Sheets from TP 139-501 for this lot number.

Marc Brovare

Quality Control Manager Signature

Title: QC Manager

Date: 10/19/23

Released Confidential