

OI-932 Page 7 of 10 Rev. X Packaged Test Strip Release Nova Max & Nova Vet

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: Pack DME 50 count NMax

Part Number: 4 3 5 2 3

BOM Rev.: F

Lot Number: 1 0 2 0 2 2 3 2 6 1

Expiration Date: 2 0 2 5 - 0 9 - 1 8

Date of Manufacture: 2 0 2 3 - 0 9 - 1 8

UDI: (01)20385480 4 3 5 2 3 3

(11) 2 3 0 9 1 8

(17) 2 5 0 9 1 8

(10) 1 0 2 0 2 2 3 2 6 1

Quantity: 7,560

Date of Release: 2 0 2 3 - 0 9 - 2 6

| 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 Browne  
Quality Control Manager Signature  
Title: Sr QC Manager

Date: 10/19/23

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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