

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 10 count Labeled NMax  
 Part Number: 43604  
 BOM Rev.: A  
 Lot Number: 1020421259  
 Expiration Date: 2023-09-16  
 Date of Manufacture: 2021-09-16  
 UDI: (01)20385480 436049  
 (11) 210916  
 (17) 230916  
 (10) 1020421259  
 Quantity: 1,925  
 Date of Release: 2021-09-23

| Release Test Results Summary  |                  |              |                    |   |     |
|---|------------------|--------------|--------------------|---|-----|
| Target Level (mg/dL)  | YSI Mean (mg/dL) | Mean (mg/dL) | SD (mg/dL) /CV (%) | SD/CV Specification   | P/F |
| 40-80   | 76.2             | 84           | 2.9                | ≤ 9 mg/dL   | P   |
| 120-180   | 174.0            | 178          | 2.9                | Fail If Both CV of this level and combined CV (L2-L5) >5.0% | P   |
| 220-300   | 291.5            | 300          | 3.5                | Fail If Both CV of this level and combined CV (L2-L5) >5.0% | P   |
| 320-440   | 416.0            | 426          | 3.6                | Fail If Both CV of this level and combined CV (L2-L5) >5.0% | P   |
| 450-550   | 488.0            | 496          | 2.5                | Fail If Both CV of this level and combined CV (L2-L5) >5.0% | P   |
| Total within ISO Zone and %: <u>360; 100.0%</u> (per ISO15197:2013) |                  |              |                    | <b>Total within ISO Zone ≥95%</b>                           | P   |

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

Maureen  
 Quality Control Manager Signature  
 Title: In QC Manager  
 Date: 9/23/2021

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