

## 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, NOVA PRO GLUCOSE, PACKAGED 1800 COUNT																								
Catalog Number:	53881																								
Nova Biomedical P/N	53881																								
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Target Range (mg/dL)</th> <th style="width: 30%;">SD(mg/dL) /CV (%)</th> <th style="width: 40%;"></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">30-50</td> <td style="text-align: center;">≤ 4 mg/dL</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> <tr> <td style="text-align: center;">51-110</td> <td style="text-align: center;">≤ 6.0%</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> <tr> <td style="text-align: center;">111-150</td> <td style="text-align: center;">≤ 5.0%</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> <tr> <td style="text-align: center;">151-250</td> <td style="text-align: center;">≤ 5.0%</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> <tr> <td style="text-align: center;">251-400</td> <td style="text-align: center;">≤ 5.0%</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> <tr> <td colspan="2">Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> <tr> <td colspan="2">Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%</td> <td style="text-align: center;">(PASS) / FAIL</td> </tr> </tbody> </table>	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	
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:	2,502																								
Lot No.	1890226026																								
Mfg. Date:	2026-01-26																								
Expiration Date:	2028-01-26																								
Unique Device Identifier (UDI):	(01)20385480538811 (11) <u>240126</u> (17) <u>280126</u> (10) <u>1890226026</u>																								

  
 \_\_\_\_\_  
 Quality Control Manager

4/3/24  
 \_\_\_\_\_  
 Date

Nova Biomedical Corporation      200 Prospect Street      Waltham, MA 02454