



**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:	N/A
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT
Catalog Number:	42214
Nova Biomedical P/N	42214
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:	4,830
Lot No.	0324178249
Mfg. Date:	2024-06-26
Expiration Date:	2024-06-27
Unique Device Identifier (UDI):	(01)20385480422141 (11)240626 (17)260627 (10)0324178249

Marc Browne  
 Quality Control Manager

7/16/2024  
 Date

Nova Biomedical Corporation    200 Prospect Street    Waltham, MA 02454