



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, STATSTRIP CAPILLARY GLUCOSE ROW, PACKAGED 100 COUNT
Catalog Number:	61500
Nova Biomedical P/N	61500
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:	500
Lot No.	0323333309
Mfg. Date:	2023-11-29
Expiration Date:	2026-05-29
Unique Device Identifier (UDI):	(01)20385480615000 (11) <u>2</u> <u>3</u> <u>1</u> <u>1</u> <u>2</u> <u>9</u> (17) <u>2</u> <u>6</u> <u>0</u> <u>5</u> <u>2</u> <u>9</u> (10) <u>0</u> <u>3</u> <u>2</u> <u>3</u> <u>3</u> <u>3</u> <u>3</u> <u>0</u> <u>9</u>

Quality Control Manager

Date

1/17/24

Nova Biomedical Corporation

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