nova biomedical

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 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	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:	5,202
Lot No.	0326041309
Mfg. Date:	2026-02-10
Expiration Date:	2028-08-10
Unique Device Identifier (UDI):	(01)20385480615000 (11)260210 (17)280810 (10)0326041309

Marc Boudreau 2/18/26

Quality Control Manager Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

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