

OI-922 Page 52 of 63 Rev. BE Vial and Packaged Test Strip Release Test Strips

nova
biomedical
CERTIFICATE OF COMPLIANCE Page 1/2

This product has been manufactured in compliance with ISO 13485:2012 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

Customer:	Nipro Diagnostics INC.
Description:	TEST STRIPS, NIPRO STATSTRIP™ GLUCOSE, PACKAGED
Catalog Number:	47940
Nova Biomedical P/N	47940
Target Range (mg/dL) Mean MPE (%) CV (%)	
60-75 ≤ 15 ≤ 6.5	PASS / FAIL
120-160 ≤ 15 ≤ 5.5	PASS / FAIL
250-290 ≤ 15 ≤ 5.0	PASS / FAIL
380-420 ≤ 15 ≤ 5.0	PASS / FAIL
500-540 ≤ 15 ≤ 5.0	PASS / FAIL
Combined MPE (%) ≤ 10%	PASS / FAIL
Qty:	303
Lot No.	2121349309
Mfg. Date:	2021-12-14
Expiration Date:	2024-06-30


Quality Control Manager

12/27/21
Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454