



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:	NIPRO DIAGNOSTICS INC.		
Description:	TEST STRIPS, NIPRO STATSTRIP™ KETONE, PACKAGED 20 CT		
Catalog Number:	54288		
Nova Biomedical P/N	54288		
<u>Target Range</u>	<u>MPE</u>	<u>SD/CV (%)</u>	
0.1-0.8 mmol/L	+ - 0.3 mmol/L	≤ 0.3 mmol/L	PASS / FAIL
1.5-2.5 mmol/L	+ - 20%	≤ 15%	PASS / FAIL
3.5-5.0 mmol/L	+ - 20%	≤ 15%	PASS / FAIL
Qty:	846		
Lot No.	2224260249		
Mfg. Date:	2024.09.17		
Expiration Date:	2026.09.30		

Maic Revore
Quality Control Manager

9/25/24
Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454