



**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	≤ 0.1 mmol/L	<u>PASS</u> FAIL
1.5-2.5 mmol/L	+/- 20%	≤ 10%	<u>PASS</u> FAIL
3.5-5.0 mmol/L	+/- 20%	≤ 10%	<u>PASS</u> FAIL
Qty:	954		
Lot No.	2225112249		
Mfg. Date:	2025.04.22		
Expiration Date:	2027.04.22		

*Marc Blome*  
 Quality Control Manager

*5/1/25*  
 Date

Nova Biomedical Corporation      200 Prospect Street      Waltham, MA 02454