

OI-922

Page 60 of 67

Rev. BN

Vialed and Packaged Test Strip Release

Test Strips

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:	LIFESCAN																		
Description:	TEST STRIPS, STATSTRIP KETONE, PACKAGED 18 BOXES OF 50 COUNT																		
Lifescan Purchase Order No.:	494370																		
Catalog Number:	46951																		
Nova Biomedical P/N	55932																		
One Touch P/N	02309002																		
<table><thead><tr><th><u>Target Range</u></th><th><u>MPE</u></th><th><u>SD/CV (%)</u></th></tr></thead><tbody><tr><td>0.1-0.8 mmol/L</td><td>+/- 0.3 mmol/L</td><td>≤ 0.1 mmol/L</td></tr><tr><td>1.5-2.5 mmol/L</td><td>+/- 20%</td><td>≤ 10%</td></tr><tr><td>3.5-5.0 mmol/L</td><td>+/- 20%</td><td>≤ 10%</td></tr></tbody></table>	<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	1.5-2.5 mmol/L	+/- 20%	≤ 10%	3.5-5.0 mmol/L	+/- 20%	≤ 10%	<table><tbody><tr><td>PASS</td><td>FAIL</td></tr><tr><td>PASS</td><td>FAIL</td></tr><tr><td>PASS</td><td>FAIL</td></tr></tbody></table>	PASS	FAIL	PASS	FAIL	PASS	FAIL
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PASS	FAIL																		
PASS	FAIL																		
PASS	FAIL																		
Qty:	2,016																		
Lot No.	2225118249																		
Date of Mfg. (DOM):	2025 / 04 / 28 (YYYY/MM/DD)																		
Expiration Date:	2027 / 04 / 28 (YYYY/MM/DD)																		
Unique Device Identifier (UDI):	(01)20385480469511 (11)250428 (17)270428 (10)2225118249																		

Marc Brune
Quality Control Manager

5/9/25
Date

Nova Biomedical Corporation

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