

OI-922

Page 61 of 67

Rev. BM

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:	NIA																					
Description:	TEST STRIPS, STATSTRIP™ KETONE, PACKAGED 50 CT																					
Catalog Number:	46951																					
Nova Biomedical P/N	46951																					
<table><thead><tr><th>Target Range</th><th>MPE</th><th>SD/CV (%)</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>	Target Range	MPE	SD/CV (%)	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>/</td><td>FAIL</td></tr><tr><td>PASS</td><td>/</td><td>FAIL</td></tr><tr><td>PASS</td><td>/</td><td>FAIL</td></tr></tbody></table>	PASS	/	FAIL	PASS	/	FAIL	PASS	/	FAIL
Target Range	MPE	SD/CV (%)																				
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%																				
PASS	/	FAIL																				
PASS	/	FAIL																				
PASS	/	FAIL																				
Qty:	33,736																					
Lot No.	2225013249																					
Mfg. Date:	2025-01-13																					
Expiration Date:	2027-01-13																					
Unique Device Identifier (UDI):	(01)20385480 469511 (11) 250113 (17) 270113 (10) 2225013249																					

Marc Broune
Quality Control Manager

1/31/25
Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454