

OI-922

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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><tr><th>Target Range</th><th>MPE</th><th>SD/CV (%)</th></tr><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></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><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr></table>	PASS / FAIL	PASS / FAIL	PASS / FAIL
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Qty:	① 21,987 18,207															
Lot No.	2224344249															
Mfg. Date:	2024-12-09															
Expiration Date:	2026-12-09															
Unique Device Identifier (UDI):	(01)20385480 469511 (11) 241209 (17) 261209 (10) 2224344249															

Mark Brosnue

Quality Control Manager

12/30/24

Date

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① MFC
12/30/24