

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 LACTATE, PACKAGED															
Catalog Number:	40813															
Nova Biomedical P/N	40813															
<table border="1"><thead><tr><th>Target Range</th><th>CV (%)</th><th>SD (mmol/L)</th></tr></thead><tbody><tr><td>0.8-2.5 mmol/L</td><td>≤ 6.5%</td><td>±0.3</td></tr><tr><td>3.0-5.0 mmol/L</td><td>≤ 5.5%</td><td>±0.5</td></tr><tr><td>10-14 mmol/L</td><td>≤ 5.0%</td><td>±1.2</td></tr></tbody></table>	Target Range	CV (%)	SD (mmol/L)	0.8-2.5 mmol/L	≤ 6.5%	±0.3	3.0-5.0 mmol/L	≤ 5.5%	±0.5	10-14 mmol/L	≤ 5.0%	±1.2	<table border="1"><tbody><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr></tbody></table>	PASS / FAIL	PASS / FAIL	PASS / FAIL
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Qty:	17,812															
Lot No.	3725041249															
Mfg. Date:	2025-02-10															
Expiration Date:	2027-02-10															
Unique Device Identifier (UDI):	(01)20385480 408138 (11) 250210 (17) 370210 (10) 3725041249															


Quality Control Manager

2/21/25
Date

Nova Biomedical Corporation

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