

OI-922

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Rev. BJ

Vialed and Packaged Test Strip Release

Test Strips



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															
<table border="1"><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>≤ 0.3 mmol/L</td></tr><tr><td>1.5-2.5 mmol/L</td><td>+/- 20%</td><td>≤ 15%</td></tr><tr><td>3.5-5.0 mmol/L</td><td>+/- 20%</td><td>≤ 15%</td></tr></tbody></table>	Target Range	MPE	SD/CV (%)	0.1-0.8 mmol/L	+/- 0.3 mmol/L	≤ 0.3 mmol/L	1.5-2.5 mmol/L	+/- 20%	≤ 15%	3.5-5.0 mmol/L	+/- 20%	≤ 15%	<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:	1,008															
Lot No.	2223306249															
Mfg. Date:	2023.11.02															
Expiration Date:	2025.11.30															

Quality Control Manager

11/22/23

Date

Nova Biomedical Corporation

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