

OI-922

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Rev. BG

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:	N/A		
Description:	TEST STRIPS, STATSTRIP LACTATE, PACKAGED		
Catalog Number:	47486		
Nova Biomedical P/N	47486		
<u>Target Range</u>	<u>CV (%)</u> <u>SD (mmol/L)</u>		
0.8-2.5 mmol/L	≤ 6.5%	±0.3	PASS / FAIL
3.0-5.0 mmol/L	≤ 5.5%	±0.5	PASS / FAIL
10-14 mmol/L	≤ 5.0%	±1.2	PASS / FAIL
Qty:	6,102		
Lot No.	2622221249		
Mfg. Date:	2022 - 08 - 09		
Expiration Date:	2024 - 08 - 09		
Unique Device Identifier (UDI):	(01)20385480 474867 (11) 220809 (17) 240809 (10) 2622221249		

MacBryne
Quality Control Manager

8/16/2022
Date

Nova Biomedical Corporation

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