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:	NIA
Description:	TEST STRIPS, STATSTRIP
•	CAPILLARY LACTATE 50 COUNT,
	PACKAGED
Catalog Number:	61440
Nova Biomedical P/N	61440
Target Range CV (%) SD (mmol/L)	
$0.8-2.5 \text{ mmol/L} \leq 6.5\% \qquad \pm 0.3$	PASS / FAIL
$3.0-5.0 \text{ mmol/L} \leq 5.5\% \qquad \pm 0.5$	PASS / FAIL
10-14 mmol/L $\leq 5.0\%$ $\pm 1.2$	PASS / FAIL
Qty:	496
Lot No.	2624120249
Mfg. Date:	2024 - 04 - 29
Expiration Date:	2026 -04 - 29
Unique Device Identifier (UDI):	(01)20385480614409
	(11) <u>2 4 0 429</u>
	$\begin{array}{c} (17)  \underline{260429} \\ (10)  \underline{2624120249} \end{array}$

Quality Control Manager

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454