

OI-922

Page 63 of 66 Rev. BJ

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, LACTATE PLUS, 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
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														
(PASS) / FAIL																
(PASS) / FAIL																
(PASS) / FAIL																
Qty:	20,988															
Lot No.	3723288249															
Mfg. Date:	2023-10-15															
Expiration Date:	2025-10-16															
Unique Device Identifier (UDI):	(01)20385480 408138 (11) 231015 (17) 251016 (10) 3723288249															

*Marc Broome*  
Quality Control Manager

*2/6/2024*  
Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454

Released Confidential