

OI-922

Page 64 of 67

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, 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><u>PASS</u> / FAIL</td></tr><tr><td><u>PASS</u> / FAIL</td></tr><tr><td><u>PASS</u> / FAIL</td></tr></tbody></table>	<u>PASS</u> / FAIL	<u>PASS</u> / FAIL	<u>PASS</u> / 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														
<u>PASS</u> / FAIL																
<u>PASS</u> / FAIL																
<u>PASS</u> / FAIL																
Qty:	10,608															
Lot No.	3725043249															
Mfg. Date:	2025-02-12															
Expiration Date:	2027-02-12															
Unique Device Identifier (UDI):	(01)20385480 <u>408138</u> (11) <u>250212</u> (17) <u>270212</u> (10) <u>3725043249</u>															



Quality Control Manager

2/26/25

Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454