



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™ KETONE, PACKAGED 50 CT																
Catalog Number:	46951																
Nova Biomedical P/N	46951																
<table border="1"> <thead> <tr> <th>Target Range</th> <th>MPE</th> <th>SD/CV (%)</th> <th></th> </tr> </thead> <tbody> <tr> <td>0.1-0.8 mmol/L</td> <td>+/- 0.3 mmol/L</td> <td>≤ 0.1 mmol/L</td> <td>PASS / FAIL</td> </tr> <tr> <td>1.5-2.5 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td>PASS / FAIL</td> </tr> <tr> <td>3.5-5.0 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td>PASS / FAIL</td> </tr> </tbody> </table>	Target Range	MPE	SD/CV (%)		0.1-0.8 mmol/L	+/- 0.3 mmol/L	≤ 0.1 mmol/L	PASS / FAIL	1.5-2.5 mmol/L	+/- 20%	≤ 10%	PASS / FAIL	3.5-5.0 mmol/L	+/- 20%	≤ 10%	PASS / FAIL	
Target Range	MPE	SD/CV (%)															
0.1-0.8 mmol/L	+/- 0.3 mmol/L	≤ 0.1 mmol/L	PASS / FAIL														
1.5-2.5 mmol/L	+/- 20%	≤ 10%	PASS / FAIL														
3.5-5.0 mmol/L	+/- 20%	≤ 10%	PASS / FAIL														
Qty:	26,460																
Lot No.	2225279249																
Mfg. Date:	2025-10-06																
Expiration Date:	2027-10-06																
Unique Device Identifier (UDI):	(01)20385480 469511 (11) 25 10 06 (17) 27 10 06 (10) 22 25 27 9249																

Mar Broome
 Quality Control Manager

10/31/25
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454