



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, NOVA MAX KETONE, PACKAGED																
Catalog Number:	53493																
Nova Biomedical P/N	53493																
<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><input checked="" type="radio"/> PASS / <input type="radio"/> FAIL</td> </tr> <tr> <td>1.5-2.5 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td><input checked="" type="radio"/> PASS / <input type="radio"/> FAIL</td> </tr> <tr> <td>3.5-5.0 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td><input checked="" type="radio"/> PASS / <input type="radio"/> FAIL</td> </tr> </tbody> </table>	Target Range	MPE	SD/CV (%)		0.1-0.8 mmol/L	+/- 0.3 mmol/L	≤ 0.1 mmol/L	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL	1.5-2.5 mmol/L	+/- 20%	≤ 10%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL	3.5-5.0 mmol/L	+/- 20%	≤ 10%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL	
Target Range	MPE	SD/CV (%)															
0.1-0.8 mmol/L	+/- 0.3 mmol/L	≤ 0.1 mmol/L	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL														
1.5-2.5 mmol/L	+/- 20%	≤ 10%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL														
3.5-5.0 mmol/L	+/- 20%	≤ 10%	<input checked="" type="radio"/> PASS / <input type="radio"/> FAIL														
Qty:	10,080																
Lot No.:	1510426019																
Mfg. Date:	2026-01-19																
Expiration Date:	2028-01-19																
Unique Device Identifier (UDI):	(01)20385480 534936 (11) 260119 (17) 280119 (10) 1510426019																

Mark Broome
 Quality Control Manager

2/6/26
 Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454