



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, 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>≤ 0.3 mmol/L</td> <td>PASS / FAIL</td> </tr> <tr> <td>1.5-2.5 mmol/L</td> <td>+ - 20%</td> <td>≤ 15%</td> <td>PASS / FAIL</td> </tr> <tr> <td>3.5-5.0 mmol/L</td> <td>+ - 20%</td> <td>≤ 15%</td> <td>PASS / FAIL</td> </tr> </tbody> </table>	Target Range	MPE	SD/CV (%)		0.1-0.8 mmol/L	+ - 0.3 mmol/L	≤ 0.3 mmol/L	PASS / FAIL	1.5-2.5 mmol/L	+ - 20%	≤ 15%	PASS / FAIL	3.5-5.0 mmol/L	+ - 20%	≤ 15%	PASS / FAIL	
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Qty:	7,560																
Lot No.:	1510724302																
Mfg. Date:	2024-10-28																
Expiration Date:	2026-10-28																
Unique Device Identifier (UDI):	(01)20385480 <u>534936</u> (11) <u>241028</u> (17) <u>261028</u> (10) <u>1510724302</u>																

Mac Browne
 Quality Control Manager

11/18/24
 Date

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