



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>≤ 0.3 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:	60,480																
Lot No.	2224263249																
Mfg. Date:	2024-09-19																
Expiration Date:	2026-09-19																
Unique Device Identifier (UDI):	(01)20385480 469511 (11)240951 (17)260951 (10)2224263249																

Marc Browne
 Quality Control Manager

10/15/24
 Date

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