




**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:	LIFESCAN																
Description:	TEST STRIPS, STATSTRIP KETONE, PACKAGED 18 BOXES OF 50 COUNT																
Lifescan Purchase Order No.:	506024																
Catalog Number:	46951																
Nova Biomedical P/N	55932																
One Touch P/N	02309002																
<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	
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Qty:	2,016																
Lot No.	2225324249																
Date of Mfg. (DOM):	2025 / 11 / 20 (YYYY/MM/DD)																
Expiration Date:	2027 / 11 / 20 (YYYY/MM/DD)																
Unique Device Identifier (UDI):	(01)20385480469511 (11)251120 (17)271120 (10)2225324249																

  
 Quality Control Manager

12/9/25  
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454

