



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.:	497601																
Catalog Number:	46951																
Nova Biomedical P/N	55932																
One Touch P/N	02309002																
<table border="0"> <thead> <tr> <th><u>Target Range</u></th> <th><u>MPE</u></th> <th><u>SD/CV (%)</u></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><u>PASS</u> / FAIL</td> </tr> <tr> <td>1.5-2.5 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td><u>PASS</u> / FAIL</td> </tr> <tr> <td>3.5-5.0 mmol/L</td> <td>+/- 20%</td> <td>≤ 10%</td> <td><u>PASS</u> / FAIL</td> </tr> </tbody> </table>	<u>Target Range</u>	<u>MPE</u>	<u>SD/CV (%)</u>		0.1-0.8 mmol/L	+/- 0.3 mmol/L	≤ 0.1 mmol/L	<u>PASS</u> / FAIL	1.5-2.5 mmol/L	+/- 20%	≤ 10%	<u>PASS</u> / FAIL	3.5-5.0 mmol/L	+/- 20%	≤ 10%	<u>PASS</u> / FAIL	
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Qty:	2,016																
Lot No.	2225169249																
Date of Mfg. (DOM):	2025 / 06 / 18 (YYYY/MM/DD)																
Expiration Date:	2027 / 06 / 18 (YYYY/MM/DD)																
Unique Device Identifier (UDI):	(01)20385480469511 (11) <u>2 5 0 6 1 8</u> (17) <u>2 7 0 6 1 8</u> (10) <u>2 2 2 5 1 6 9 2 4 9</u>																


 Quality Control Manager

7/1/25
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454