



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, LIFESCAN ONETOUCH STATSTRIP GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT																												
Lifescan Purchase Order No.:																													
Catalog Number:	017010D592315																												
Nova Biomedical P/N	N/A																												
One Touch P/N	53995																												
One Touch P/N	02334001																												
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Target Range (mg/dL)</th> <th style="text-align: left;">Mean MPE (%)</th> <th style="text-align: left;">CV (%)</th> <th></th> </tr> </thead> <tbody> <tr> <td>60-75</td> <td>≤ 15</td> <td>≤ 6.5</td> <td>PASS / FAIL</td> </tr> <tr> <td>120-160</td> <td>≤ 15</td> <td>≤ 5.5</td> <td>PASS / FAIL</td> </tr> <tr> <td>250-290</td> <td>≤ 15</td> <td>≤ 5.0</td> <td>PASS / FAIL</td> </tr> <tr> <td>380-420</td> <td>≤ 15</td> <td>≤ 5.0</td> <td>PASS / FAIL</td> </tr> <tr> <td>500-540</td> <td>≤ 15</td> <td>≤ 5.0</td> <td>PASS / FAIL</td> </tr> <tr> <td>Combined MPE (%)</td> <td>≤ 10</td> <td></td> <td>PASS / FAIL</td> </tr> </tbody> </table>	Target Range (mg/dL)	Mean MPE (%)	CV (%)		60-75	≤ 15	≤ 6.5	PASS / FAIL	120-160	≤ 15	≤ 5.5	PASS / FAIL	250-290	≤ 15	≤ 5.0	PASS / FAIL	380-420	≤ 15	≤ 5.0	PASS / FAIL	500-540	≤ 15	≤ 5.0	PASS / FAIL	Combined MPE (%)	≤ 10		PASS / FAIL	
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Qty:	6,012																												
Lot No.	0319280309																												
Date of Mfg. (DOM):	2019 / 10 / 01 (YYYY/MM/DD)																												
Expiration Date:	2022 / 04 (YYYY/MM)																												

Mar Brune
Quality Control Manager

11/7/19
Date

Nova Biomedical Corporation

200 Prospect Street Waltham, MA 02454



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