

OI 922 Page 30 of 62 Rev. AY Vial and Packaged Test Strip Release Test Strips



CERTIFICATE OF COMPLIANCE

This product has been manufactured in compliance with CFR 21- Part 820, ISO 13485:2012, and meets Nova Biomedical product specifications.

Customer:	N/A																											
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 1800 COUNT																											
Catalog Number:	42214																											
Nova Biomedical P/N	55890																											
<table border="1"> <thead> <tr> <th>Target Range (mg/dL)</th> <th>Mean MPE (%)</th> <th>CV (%)</th> </tr> </thead> <tbody> <tr> <td>60-75</td> <td>≤ 15</td> <td>≤ 6.5</td> </tr> <tr> <td>120-160</td> <td>≤ 15</td> <td>≤ 5.5</td> </tr> <tr> <td>250-290</td> <td>≤ 15</td> <td>≤ 5.0</td> </tr> <tr> <td>380-420</td> <td>≤ 15</td> <td>≤ 5.0</td> </tr> <tr> <td>500-540</td> <td>≤ 15</td> <td>≤ 5.0</td> </tr> <tr> <td>Combined MPE (%)</td> <td>≤ 10%</td> <td></td> </tr> </tbody> </table>	Target Range (mg/dL)	Mean MPE (%)	CV (%)	60-75	≤ 15	≤ 6.5	120-160	≤ 15	≤ 5.5	250-290	≤ 15	≤ 5.0	380-420	≤ 15	≤ 5.0	500-540	≤ 15	≤ 5.0	Combined MPE (%)	≤ 10%		<table border="1"> <tbody> <tr> <td>PASS / FAIL</td> </tr> <tr> <td>PASS / FAIL</td> </tr> <tr> <td>PASS / FAIL</td> </tr> <tr> <td>PASS / FAIL</td> </tr> <tr> <td>PASS / FAIL</td> </tr> <tr> <td>PASS / FAIL</td> </tr> </tbody> </table>	PASS / FAIL	PASS / FAIL	PASS / FAIL	PASS / FAIL	PASS / FAIL	PASS / FAIL
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Qty:	832																											
Lot No.	0319072249																											
Mfg. Date:	2019/03/13																											
Expiration Date:	2021/03/13																											
Unique Device Identifier (UDI):	(01)20385480422141 (11)190313 (17)210313 (10)0319072249																											

Mark Brosne
Quality Control Manager

4/16/19
Date

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