

OI-922

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Rev. BH

Vialed and Packaged Test Strip Release

Test Strips



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™ GLUCOSE, PACKAGED 1800 COUNT																											
Catalog Number:	42214																											
Nova Biomedical P/N	42214																											
<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 colspan="2">≤ 10%</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:	3,735																											
Lot No.	0323206249																											
Mfg. Date:	2023-07-25																											
Expiration Date:	2025-07-26																											
Unique Device Identifier (UDI):	(01)20385480422141 (11)230725 (17)250726 (10)0323206249																											

Mark Broome
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8/23/2023
Date

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