



CERTIFICATE OF CONFORMANCE AND ANALYSIS

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:	TRIVIDIA HEALTH, INC.																																			
Product Name:	TRUE FOCUS Test Strips																																			
Description:	TEST STRIPS, 50 CT. VIALED, TRUE FOCUS GLUCOSE																																			
Trividia Health P/N:	99527-50a																																			
Nova Biomedical P/N:	51985																																			
Reference Methods:	Glucose- YSI 2300																																			
<table border="1"> <thead> <tr> <th>Target Range (mg/dL)</th> <th>Mean MPE (%)</th> <th>CV (%)</th> <th>Mean MPE (%)</th> <th>CV (%)</th> </tr> </thead> <tbody> <tr> <td>60-90</td> <td>≤ 15</td> <td>≤ 6.5</td> <td>13.2 (PASS) / FAIL</td> <td>4.1 (PASS) / FAIL</td> </tr> <tr> <td>120-160</td> <td>≤ 15</td> <td>≤ 5.5</td> <td>5.6 (PASS) / FAIL</td> <td>4.1 (PASS) / FAIL</td> </tr> <tr> <td>250-290</td> <td>≤ 15</td> <td>≤ 5.0</td> <td>3.3 (PASS) / FAIL</td> <td>3.0 (PASS) / FAIL</td> </tr> <tr> <td>380-420</td> <td>≤ 15</td> <td>≤ 5.0</td> <td>2.0 (PASS) / FAIL</td> <td>2.2 (PASS) / FAIL</td> </tr> <tr> <td>500-540</td> <td>≤ 15</td> <td>≤ 5.0</td> <td>3.7 (PASS) / FAIL</td> <td>4.5 (PASS) / FAIL</td> </tr> <tr> <td>Combined MPE (%)</td> <td>≤ 10%</td> <td></td> <td>5.5 (PASS) / FAIL</td> <td></td> </tr> </tbody> </table>	Target Range (mg/dL)	Mean MPE (%)	CV (%)	Mean MPE (%)	CV (%)	60-90	≤ 15	≤ 6.5	13.2 (PASS) / FAIL	4.1 (PASS) / FAIL	120-160	≤ 15	≤ 5.5	5.6 (PASS) / FAIL	4.1 (PASS) / FAIL	250-290	≤ 15	≤ 5.0	3.3 (PASS) / FAIL	3.0 (PASS) / FAIL	380-420	≤ 15	≤ 5.0	2.0 (PASS) / FAIL	2.2 (PASS) / FAIL	500-540	≤ 15	≤ 5.0	3.7 (PASS) / FAIL	4.5 (PASS) / FAIL	Combined MPE (%)	≤ 10%		5.5 (PASS) / FAIL		
Target Range (mg/dL)	Mean MPE (%)	CV (%)	Mean MPE (%)	CV (%)																																
60-90	≤ 15	≤ 6.5	13.2 (PASS) / FAIL	4.1 (PASS) / FAIL																																
120-160	≤ 15	≤ 5.5	5.6 (PASS) / FAIL	4.1 (PASS) / FAIL																																
250-290	≤ 15	≤ 5.0	3.3 (PASS) / FAIL	3.0 (PASS) / FAIL																																
380-420	≤ 15	≤ 5.0	2.0 (PASS) / FAIL	2.2 (PASS) / FAIL																																
500-540	≤ 15	≤ 5.0	3.7 (PASS) / FAIL	4.5 (PASS) / FAIL																																
Combined MPE (%)	≤ 10%		5.5 (PASS) / FAIL																																	
Control Ranges (mg/dL):	Level 1: <u>35 - 65</u> mg/dL Level 2: <u>85 - 125</u> mg/dL Level 3: <u>240 - 340</u> mg/dL																																			
Lot Qty:	30,401																																			
Lot No.	1650824225																																			
Mfg. Date (YYYY-MM-DD):	2024-08-12																																			
Expiration Date (YYYY-MM-DD):	2026-11-12																																			

Marc Brune 8/22/2024
 Quality Control Manager Signature Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454