UNISTRIP1™

GENERIC

Blood Glucose Test Strips

ONETOUCH®

Ultra® Blue

Test Strips

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1. Purpose

This study is intended to evaluate the difference in values obtained from the same samples of capillary whole blood when using the OneTouch® Ultra® Blood Glucose Meter and the UniStrip1™ Test Strip and the OneTouch® Ultra® Blue Test Strip.

2. Supporting Documents

2.1 FDA Guidance Document: Review Criteria of Portable Blood Glucose Monitoring In vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. 02/28/1997

2.2 ISO 15197:2013, In vitro diagnostic test systems-Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

2.3 ISO 5725-1:1994 Accuracy (trueness and precision) of measurement methods and results -- Part 1: General principles and definitions

2.4 Clarke, WL, Cox D, Gonder-Frederick LA, et al: Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose, Diabetes Care 10: 622-628, 1987.

3. Principle

The principle method for an amperometric system to determine the amounts of β-D-glucose in a sample was from oxidation of glucose by glucose oxidase contained in a sensor strip. Then the electric current produced during the oxidation process was received and measured by a blood glucose meter to evaluate the amounts of electrons released in the oxidation process, thus the meter could transfer the size of current into the concentration of glucose in the sample.

4. Cautions

Standard laboratory safety practice including protective eye wear along with those specificities for handling blood products should be followed. Blood samples should be handled in a glove box.

5. Materials

5.1 2 OneTouch® Ultra® Blood Glucose Meters.

5.2 UniStrip1™ Test Strips and OneTouch® Ultra® Blue Test Strips, all of which were obtained from the same production lot.

6. Procedure

6.1 The technician shall obtain capillary blood sample from participant's finger by lancing.

6.2 Measure the finger capillary blood by UniStrip1™ Test Strip with OneTouch® Ultra® Blood Glucose Meter.

6.3 Immediately duplicate Step 6.2 with another UniStrip1™ Test Strip with the same OneTouch® Ultra® Blood Glucose Meter.

6.4 Measure the finger capillary blood by OneTouch® Ultra® Blue Test Strip with OneTouch® Ultra® Blood Glucose Meter.

6.5 Immediately duplicate Step 6.1 with another OneTouch® Ultra® Blue Test Strip with the same OneTouch® Ultra® Blood Glucose Meter.

6.6 Ensure that the same OneTouch® Ultra® Blood Glucose Meter is used for all testing for each blood sample. Different meters can be used throughout the study, but different meters should not be used for each of steps 6.1 through 6.5 for the same sample.

7. Data analysis

7.1 The data will be analyzed to determine the average difference in values obtained by testing a blood sample for blood glucose levels with the UniStrip1™ and the OneTouch® Ultra® Bluetest strips when using the same Ultra blood glucose meter. The differences will be measured in whole values stated as mg/dL, and as a percentage of the blood glucose value (e.g., average difference divided by average value).

8. Test results and data summary

The raw data from the test results obtained from the procedures in Section 6, from 100 live participants, is shown in Table 1 at the end of this report.

8.1 Testing Results Comparison

8.1.1 The average blood glucose value was determined by adding all of the values in the four columns and dividing that number (60,751) by 400, which equals 151.88.

8.1.2 The average difference in measurements using the UniStrip1™ and the OneTouch® Ultra® Blue test strips, presented as X.XX mg/dL, is as follows:

Measurement 1(UniStrip1) vs Measurement 1(Ultra Blue):	8.46 mg/dL
Measurement 1(UniStrip1) vs Measurement 2(Ultra Blue):	8.36 mg/dL
Measurement 2(UniStrip1) vs Measurement 1(Ultra Blue):	10.04 mg/dL
Measurement 2(UniStrip1) vs Measurement 2(Ultra Blue):	8.88 mg/dL
Total:	8.93 mg/dL

8.1.3 To determine the average difference in measurements using the UniStrip1™ and the OneTouch® Ultra® Blue test strips, with the same OneTouch® Ultra® meter, presented as a percentage of the blood glucose levels, the average difference (8.93) was divided by the average value (151.88), which equals 5.88%

9. Conclusion

Based on the information set forth above, we conclude that the UniStrip1™ Test Strip provides a substantially similar reading to that obtained with the OneTouch® Ultra® Blue Test Strip, with an average variance of only 5.88% of the blood glucose values.

Raw Data - *Table 1: Raw Data from Blood Samples Obtained from Procedures in Section 6*

NO.	Gender	Age	AC /PC	PC (min)	HCT	OneTouch Ultra Blue-1	OneTouch Ultra Blue-1	UniStrip-1	UniStrip-2
1	Male	51	AC		43.3	143	147	137	141
2	Female	83	PC	110	40.2	136	146	137	145
3	Female	82	PC	30	44.2	193	189	197	189
4	Female	56	PC	40	41.8	124	119	118	126
5	Male	70	PC	75	40.8	201	213	218	228
6	Male	65	AC		38.2	117	108	123	121
7	Female	50	PC	65	47.2	183	195	200	194
8	Female	83	AC		44.2	121	131	122	129
9	Female	59	PC	125	43.6	180	179	196	199
10	Female	57	PC	15	44.1	145	159	158	140
11	Female	74	AC		48.0	93	96	98	108
12	Male	69	PC	130	39.9	114	121	115	111
13	Male	55	PC	85	38.7	225	231	244	279
14	Male	51	PC	150	37.8	133	126	124	123
15	Female	49	PC	45	44.2	74	80	74	77
16	Male	66	PC	225	47.7	231	211	192	191
17	Male	54	AC		40.1	168	160	148	146
18	Female	63	PC	60	38.8	149	145	149	151
19	Female	41	PC	195	37.6	275	274	252	249
20	Male	48	AC		47.4	111	112	110	115
21	Female	60	PC	60	36.9	244	250	241	247
22	Female	77	AC		41.5	142	172	149	144
23	Male	76	AC		41.8	140	137	134	142
24	Male	82	AC		42.7	145	144	144	157
25	Female	71	AC		30.5	176	181	180	183
26	Male	76	AC		45.6	185	203	192	227
27	Female	81	AC		41.3	138	143	146	139
28	Female	64	PC	45	34.2	266	266	267	266
29	Female	49	AC		39.7	145	39 1	42	141
30	Female	84	AC		39.0	139	132	141	145
31	Male	50	AC		47.2	129	145	140	142
32	Male	71	PC	60	38.9	103	105	107	113
33	Female	72	AC		39.3	117	116	114	108
34	Male	74	AC		42.0	112	109	119	118
35	Male	75	AC		43.2	178	174	189	200
36	Male	66	PC	60	42.3	238	225	217	230

NO.	Gender	Age	AC /PC	PC (min)	HCT	OneTouch Ultra Blue-1	OneTouch Ultra Blue-1	UniStrip-1	UniStrip-2
37	Female	71	AC		41.9	137	132	149	156
38	Female	46	PC	30	37.8	116	111	115	114
39	Male	48	AC		47.1	154	158	156	160
40	Male	41	AC		50.6	109	109	118	128
41	Female	68	AC		31.5	91	90	92	104
42	Male	51	AC		41.6	100	111	109	111
43	Male	58	AC		41.0	88	93	93	94
44	Male	66	PC	155	46.0	126	125	126	124
45	Male	65	PC	55	42.5	225	225	225	213
46	Female	77	AC		38.5	122	117	124	120
47	Male	42	PC	145	48.8	116	120	107	109
48	Female	40	AC		43.9	145	155	138	151
49	Female	72	AC		38.8	131	119	127	119
50	Female	68	AC		33.1	113	120	125	117
51	Female	66	AC		43.2	136	130	113	117
52	Female	63	AC		43.0	107	107	113	99
53	Male	68	AC		45.0	142	142	126	144
54	Female	63	AC		46.1	131	131	125	126
55	Female	56	PC	30	44.1	149	155	139	141
56	Male	78	PC	60	44.6	116	127	110	112
57	Male	45	AC		47.3	89	96	101	97
58	Female	60	AC		43.5	140	147	144	143
59	Female	72	PC	65	40.0	129	139	125	134
60	Female	42	PC	60	42.6	131	138	132	135
61	Male	72	PC	190	44.2	110	123	110	103
62	Male	71	PC	170	41.0	140	143	120	146
63	Female	55	AC		40.4	132	130	130	131
64	Male	37	AC		39.2	120	113	123	116
65	Male	56	AC		40.7	142	140	147	135
66	Male	53	PC	65	46.0	126	122	116	121
67	Female	55	AC		38.0	123	105	110	111
68	Male	53	AC		48.6	132	124	101	103
69	Female	71	PC	120	42.5	140	132	124	124
70	Male	78	AC		42.3	131	131	129	139
71	Male	61	PC	25	48.3	228	211	212	218
72	Male	71	PC	125	46.2	175	182	192	182

NO.	Gender	Age	AC /PC	PC (min)	HCT	OneTouch Ultra Blue-1	OneTouch Ultra Blue-1	UniStrip-1	UniStrip-2
73	Male	74	PC	35	45.8	207	191	190	178
74	Female	64	AC		46.3	167	157	164	179
75	Female	78	AC		38.2	113	106	114	112
76	Male	49	PC	80	41.8	191	184	198	202
77	Male	60	PC	90	35.3	190	190	193	194
78	Male	53	AC		29.2	183	184	178	177
79	Male	78	AC		35.9	136	129	124	123
80	Female	60	AC		42.7	141	140	133	137
81	Male	72	PC	135	42.6	343	373	402	381
82	Male	66	PC	140	41.9	152	150	147	139
83	Female	79	PC	40	31.5	270	265	284	289
84	Female	77	PC	100	37.2	176	176	177	176
85	Male	73	AC		27.2	125	120	124	126
86	Female	72	PC	95	44.1	138	154	150	150
87	Male	80	PC	190	41.4	246	251	260	273
88	Female	60 P	C	105	42.5	138	131	135	136
89	Male	59	PC	170	36.8	78	80	78	79
90	Female	61	PC	80	41.6	177	197	177	204
91	Female	76	PC	180	39.7	148	148	159	158
92	Female	70	PC	120	40.8	126	140	120	121
93	Female	64	PC	120	32.1	87	95	87	87
94	Female	65	AC		35.3	147	134	127	127
95	Female	64	PC	120	37.0	151	148	133	140
96	Female	61	AC		41.5	122	120	117	113
97	Male	71	PC	135	45.4	101	112	103	98
98	Female	70	PC	80	38.4	203	197	209	202
99	Male	81	PC	55	35.5	245	231	221	237
100	Female	71	PC	80	33.2	193	192	196	186

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