keto mojo

Blood Glucose Monitoring System Comparison Report (Keto-Mojo GK+, Keto-Mojo TD-4279, Abbott Precision Xtra, Accu-Chek Performa)

Comparison Report

1.0 Objective

The objective of the comparison report is to demonstrate the accuracy of the Keto-Mojo GK+, Keto-Mojo TD-4279, Abbott Precision Xtra, and Accu-Chek Performa blood glucose monitoring systems when compared to a laboratory reference measurement method (YSI 2900). The study was performed with fresh fingertip blood samples.

2.0 Materials

2.1 Keto-Mojo GK+ Blood Glucose and β-Ketone Test Meters

2.2 Keto-Mojo GK+ Blood Glucose Test Strips

2.3 Keto-Mojo TD-4279 Blood Glucose and β-Ketone Test Meters

2.4 Keto-Mojo TD-4279 Blood Glucose Test Strips

2.5 Abbott Precision Xtra Blood Glucose and β-Ketone Test Meters

2.6 Abbott Precision Xtra Blood Glucose Test Strips

2.7 Accu-Chek Performa Blood Glucose Test Meters

2.8 Accu-Chek Performa Blood Glucose Test Strips

3.0 Environmental Conditions:

The study temperature was 74.6 F (23.7 ℃).

4.0 Acceptance Criteria

95% of measured glucose results shall fall within either ±15% of the reference measurement procedure (YSI), and 100% of measured glucose results shall fall within either ±20% of the reference measurement procedure (YSI). (FDA OTC Guidance)

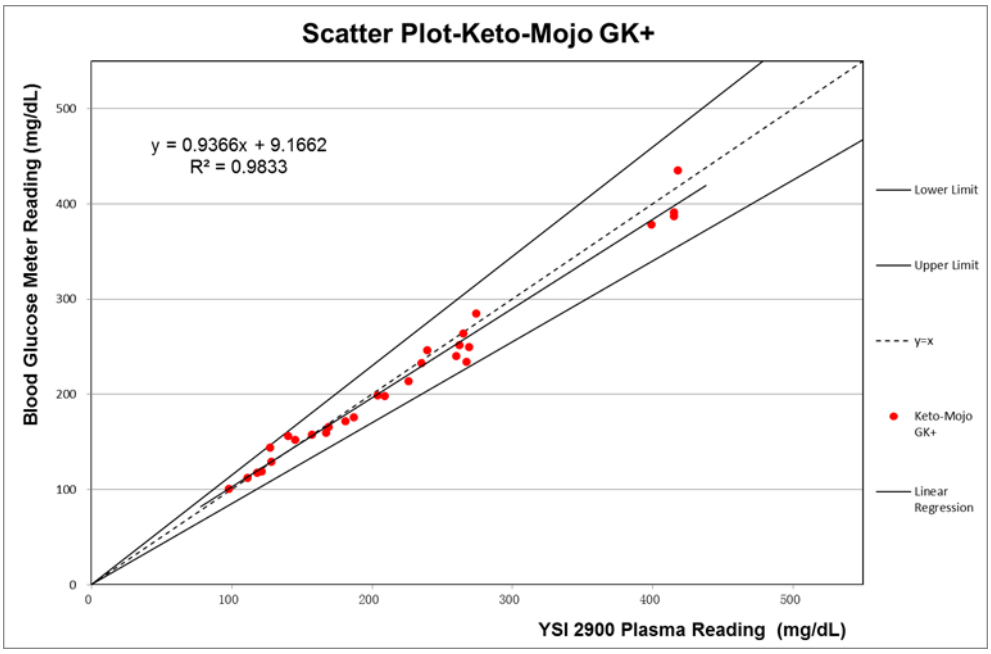
99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG). (ISO 15197:2013 (E), Section 6.3.3)

5.0 Results

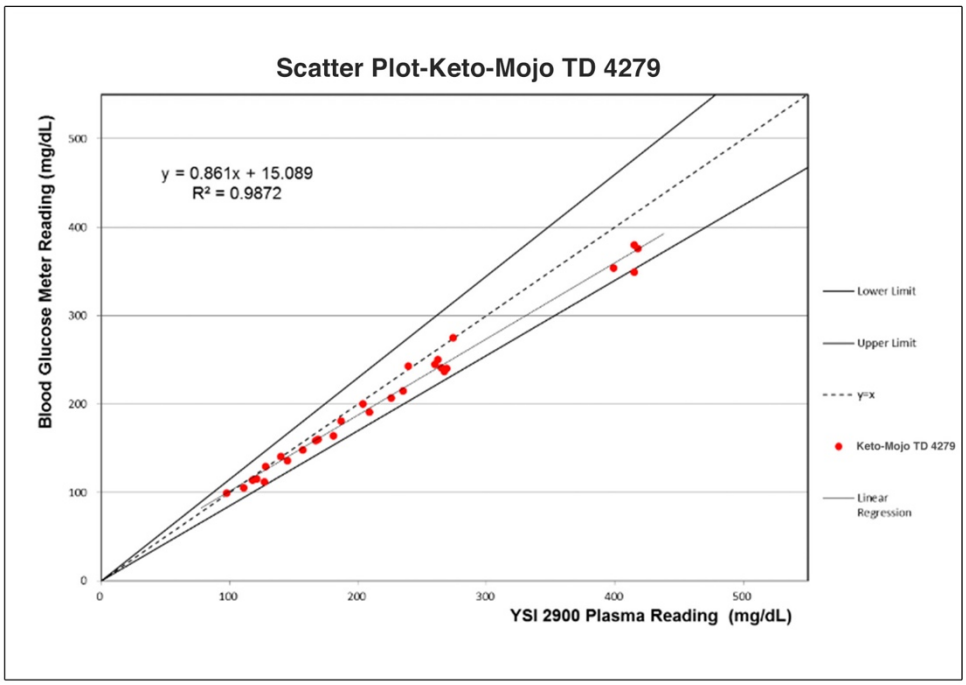
Test results were analyzed by using "Regression Analysis Method," "Consensus Error Grid Analysis" and "Difference Plot Method."

5.1 Scatter Plot

5.1.1 Keto-Mojo GK+ vs. YSI 2900

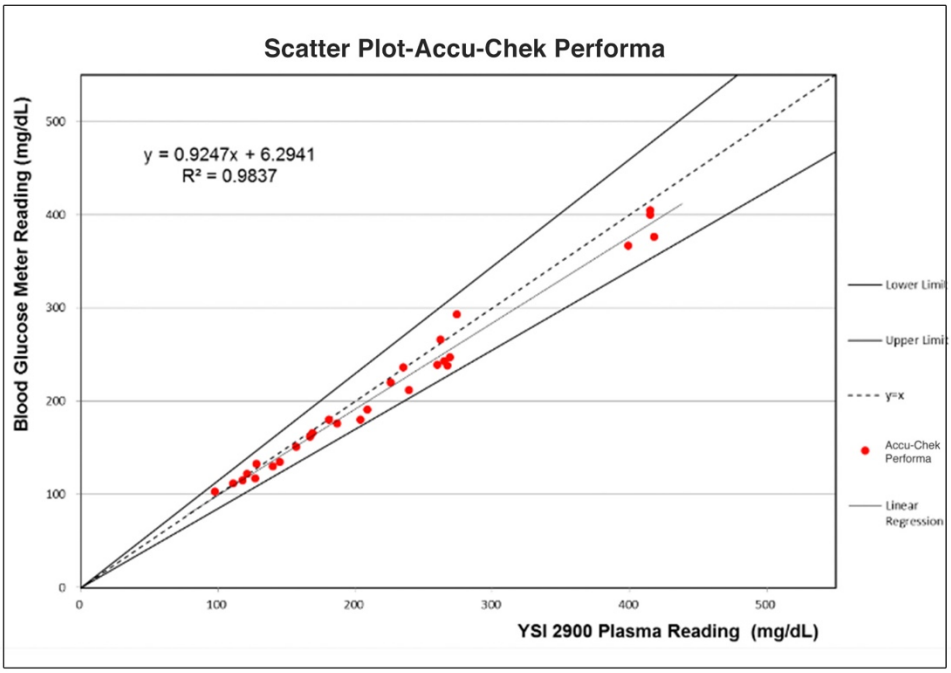


5.1.2 Keto-Mojo TD-4279 vs. YSI 2900



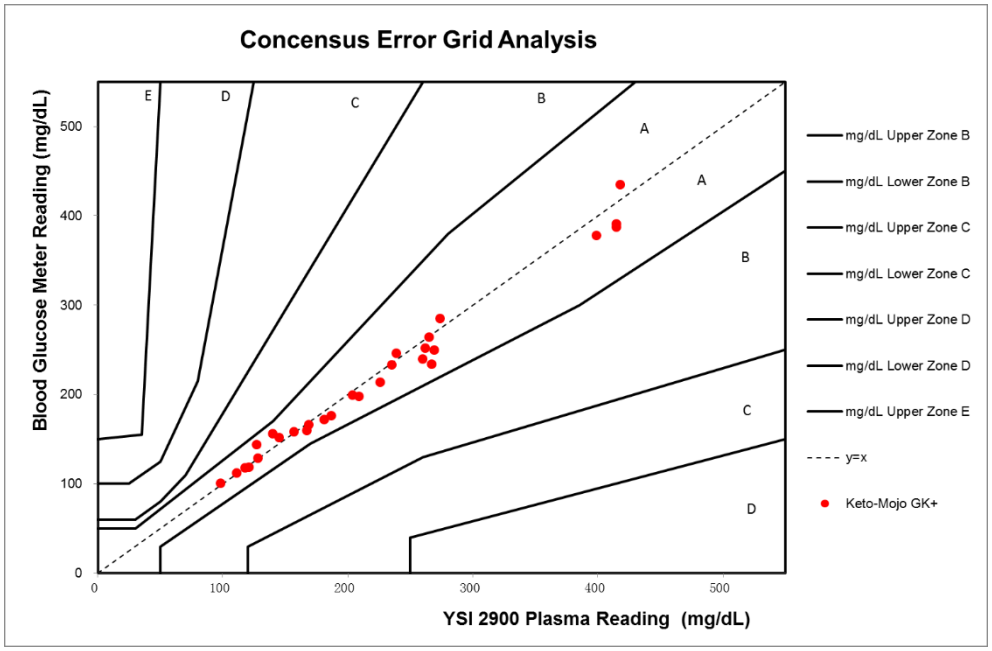
5.1.3 Abbott Precision Xtra vs. YSI 2900

5.1.4 Accu-Chek Performa vs. YSI 2900

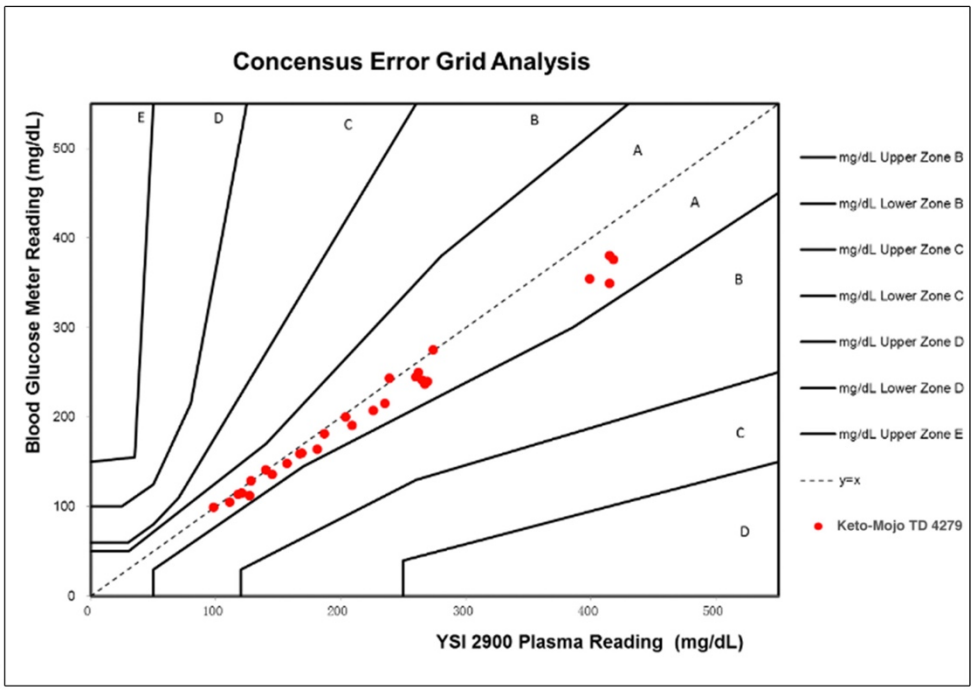


5.2 Consensus Error Grid Analysis

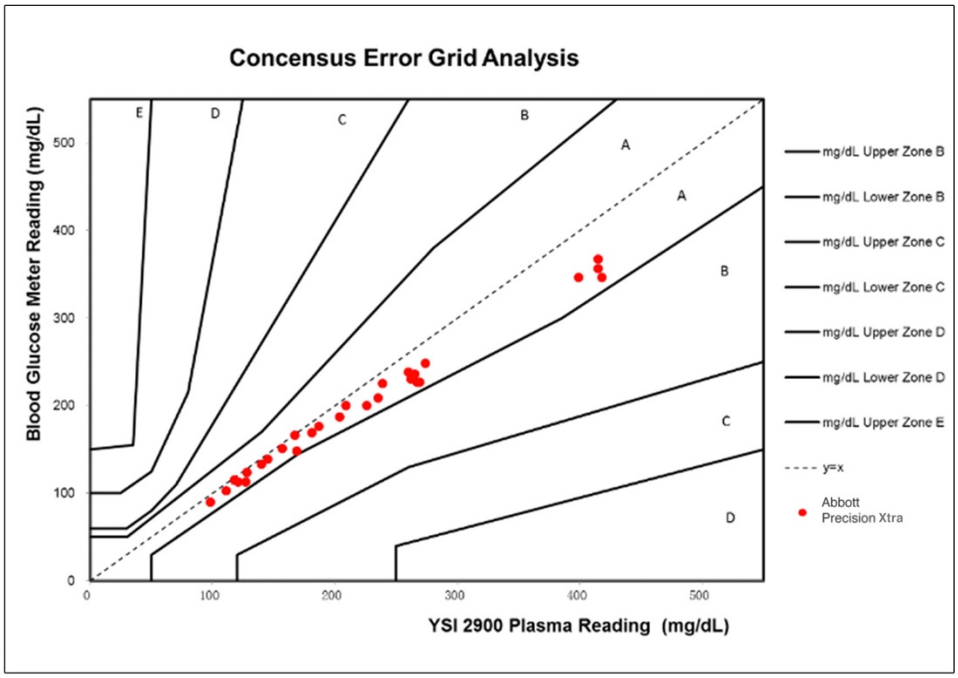
5.2.1 Keto-Mojo GK+ vs. YSI 2900



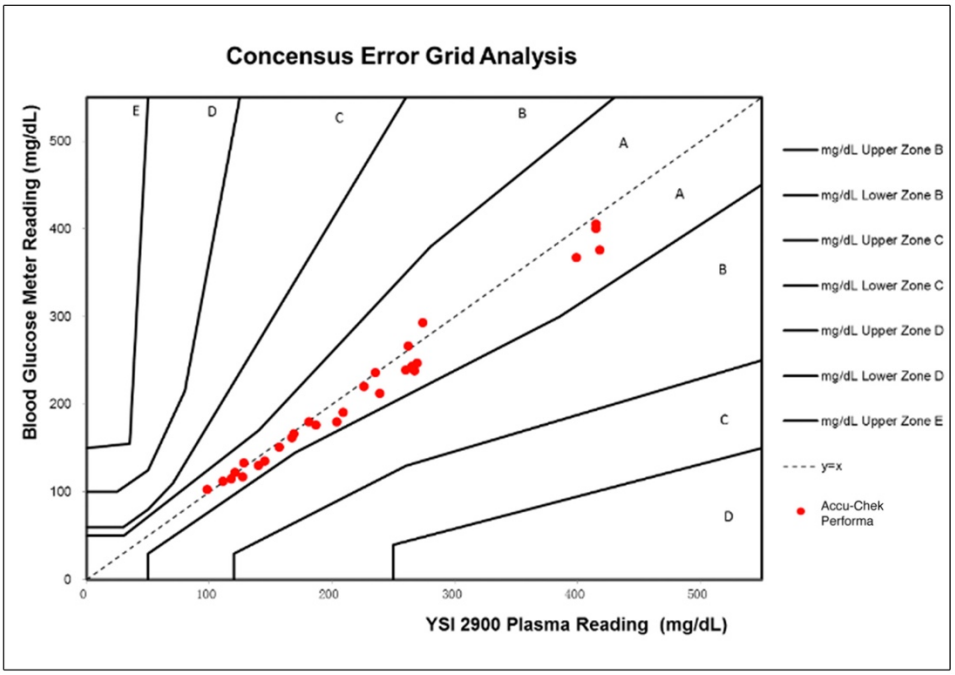
5.2.2 Keto-Mojo TD-4279 vs. YSI 2900



5.2.3 Abbott Precision Xtra vs. YSI 2900

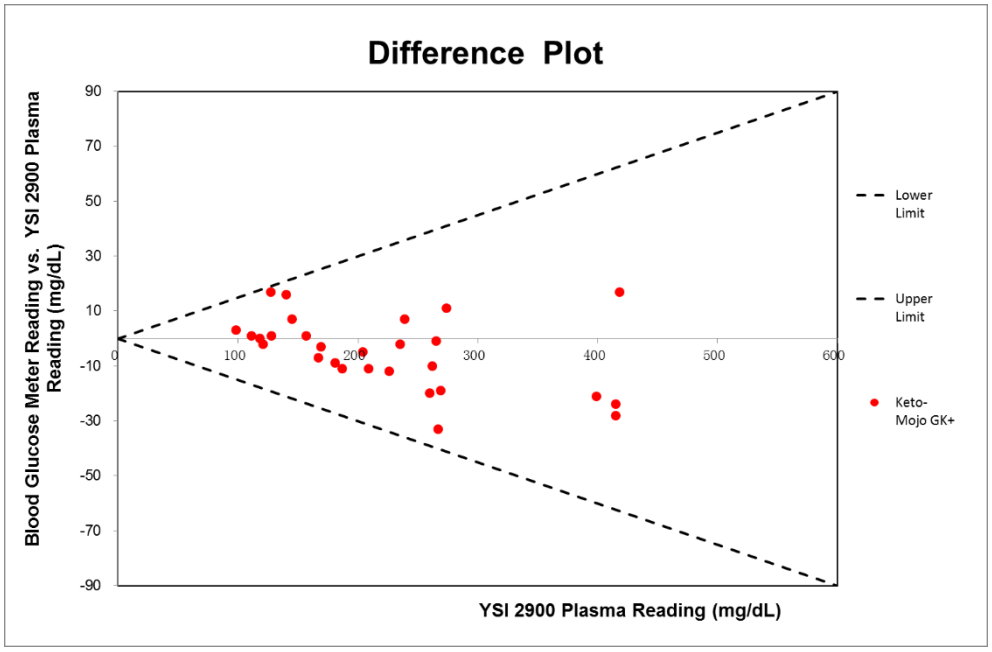


5.2.4 Accu-Check Performa vs. YSI 2900

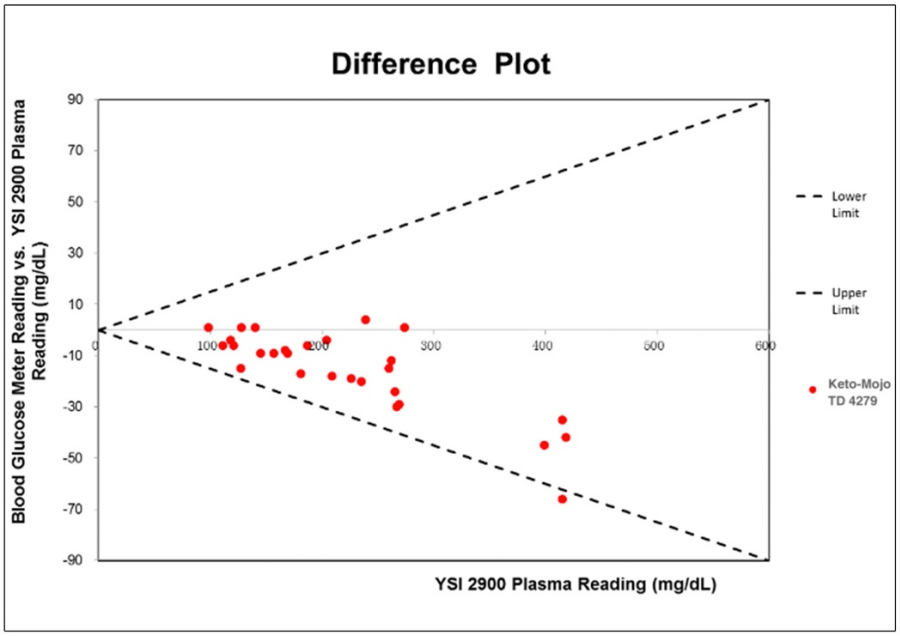


5.3 Difference Plot

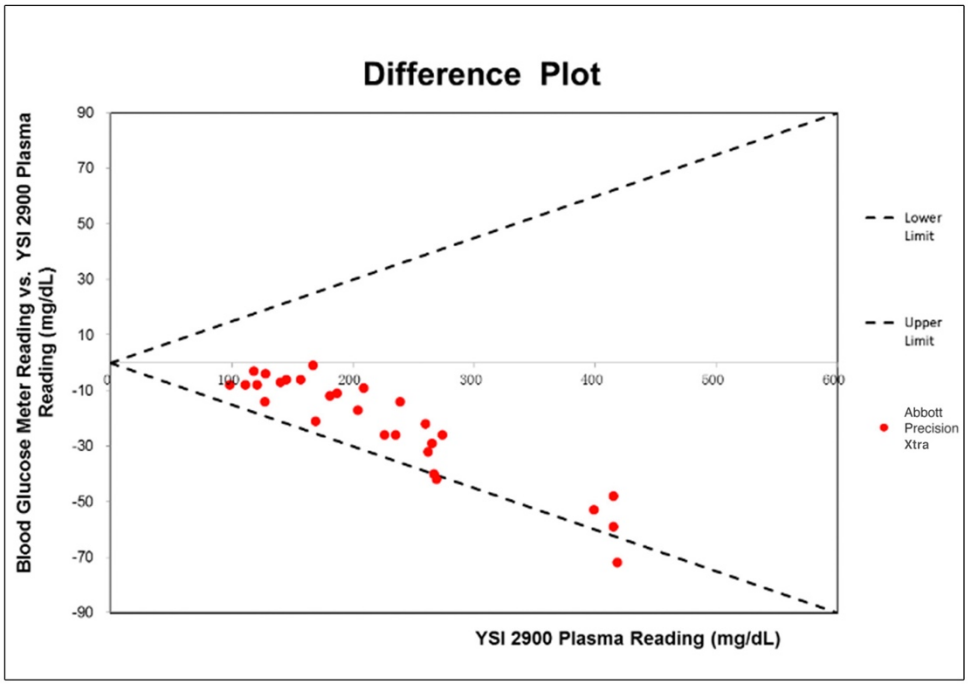
5.3.1 Keto-Mojo GK+ vs. YSI 2900



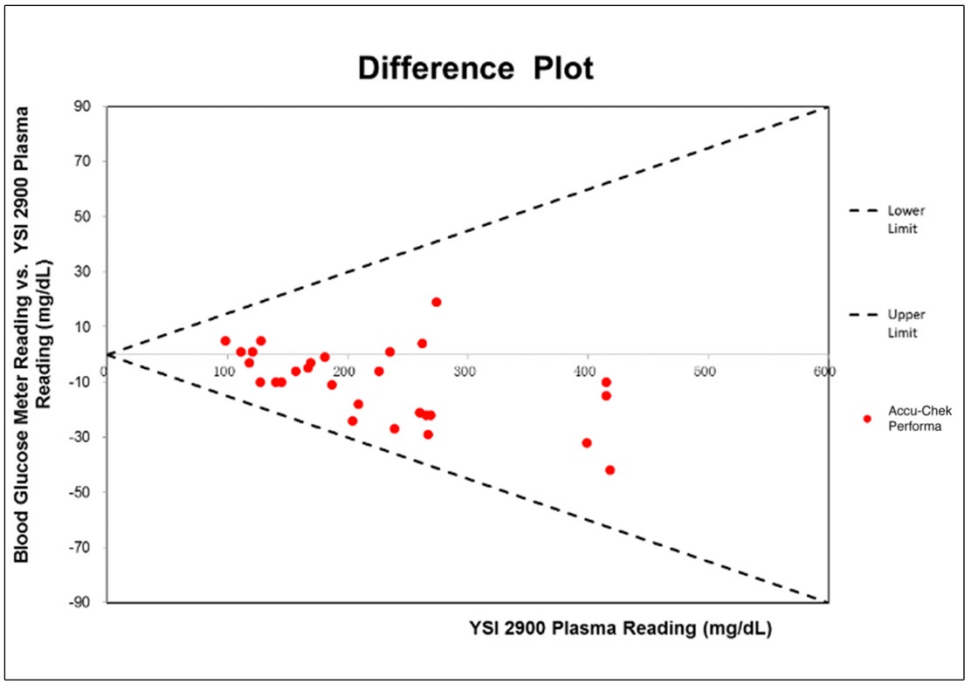
5.3.2 Keto-Mojo TD-4279 vs. YSI 2900



5.3.3 Abbott Precision Xtra vs YSI 2900



5.3.4 Accu-Chek Performa vs YSI 2900



5.4 Data Table

Blood Glucose Reading						Blood Glucose Meter Reading vs. YSI 2900 Plasma Reading			
Sample No	Keto-Mojo GK+	Keto-Mojo TD4279	Abbott	Accu-Chek	YSI 2900	Keto-Mojo GK+	Keto-Mojo TD 4279	Abbott	Accu-Chek
1	285	275	248	293	274	4.0%	0.4%	-9.5%	6.9%
2	234	237	227	238	267	-12.4%	-11.2%	-15.0%	-10.9%
3	129	129	124	133	128	0.8%	0.8%	-3.1%	3.9%
4	119	115	113	122	121	-1.7%	-5.0%	-6.6%	0.8%
5	252	250	230	266	262	-3.8%	-4.6%	-12.2%	1.5%
6	118	114	115	115	118	0.0%	-3.4%	-2.5%	-2.5%
7	152	136	139	135	145	4.8%	-6.2%	-4.1%	-6.9%
8	166	160	148	166	169	-1.8%	-5.3%	-12.4%	-1.8%
9	214	207	200	220	226	-5.3%	-8.4%	-11.5%	-2.7%
10	144	112	113	117	127	13.4%	-11.8%	-11.0%	-7.9%
11	240	245	238	239	260	-7.7%	-5.8%	-8.5%	-8.1%
12	112	105	103	112	111	0.9%	-5.4%	-7.2%	0.9%
13	101	99	90	103	98	3.1%	1.0%	-8.2%	5.1%
14	172	164	169	180	181	-5.0%	-9.4%	-6.6%	-0.6%
15	199	200	187	180	204	-2.5%	-2.0%	-8.3%	-11.8%
16	246	243	225	212	239	2.9%	1.7%	-5.9%	-11.3%
17	156	141	133	130	140	11.4%	0.7%	-5.0%	-7.1%
18	233	215	209	236	235	-0.9%	-8.5%	-11.1%	0.4%
19	160	159	166	162	167	-4.2%	-4.8%	-0.6%	-3.0%
20	435	376	346	376	418	4.1%	-10.0%	-17.2%	-10.0%
21	387	349	367	405	415	-6.7%	-15.9%	-11.6%	-2.4%
22	378	354	346	367	399	-5.3%	-11.3%	-13.3%	-8.0%
23	158	148	151	151	157	0.6%	-5.7%	-3.8%	-3.8%
24	176	181	176	176	187	-5.9%	-3.2%	-5.9%	-5.9%
25	198	191	200	191	209	-5.3%	-8.6%	-4.3%	-8.6%
26	264	241	236	243	265	-0.4%	-9.1%	-10.9%	-8.3%
27	250	240	227	247	269	-7.1%	-10.8%	-15.6%	-8.2%
28	391	380	356	400	415	-5.8%	-8.4%	-14.2%	-3.6%

6.0 Conclusion

The results showed that the Keto-Mojo GK+ Blood Glucose and β-Ketone Monitoring System meets the system accuracy performance criteria.