

Lipid Testing System Clinical Study

I. Instruction

The BOSURE Lipid testing system is a quick, simple and reliable quantitative test to detect the concentration of TC, HDL and TG in whole blood/plasma/serum. The handheld lipid meter can report quantitative result basing on the reaction of the associating lipid test device.

II. Study Objective

To perform a correlation study:

BOSURE Lipid testing system vs. PTS cholesterol test system

III. Specimen Collection

Total 100 patients took part in this clinical study. These 100 patients donated the venous whole blood in heparin tubes. All the samples were tested in 8 hours after collected and mixed well before test.

IV. Materials

1. BOSURE 3 in 1 Lipid test device (lot CH18040002)
2. PTS 3 in 1 Lipid test device (lot P218)
3. BOSURE Lipid testing system (SN 12100001011)
4. PTS cholesterol meter (SN 864113)

V. Methods

1. The total amount of clinical specimens for this study is 100.
2. Perform the BOSUE 3 in 1 lipid test device on BOSURE meter with clinical blood specimens. Record the test result.
3. Perform the PTS cholesterol test device on PTS meter with same clinical blood specimens and record the test result.
4. Make three plots of the data. One is a scatter plot of TC results of BOSURE Lipid test system VS that of PTS cholesterol test system. The second one is a scatter plot of HDL results of BOSURE Lipid test system VS that of PTS cholesterol test system. The third one is a scatter plot of the TG results of BOSURE Lipid test system VS that of PTS cholesterol test system.

VI. Reports

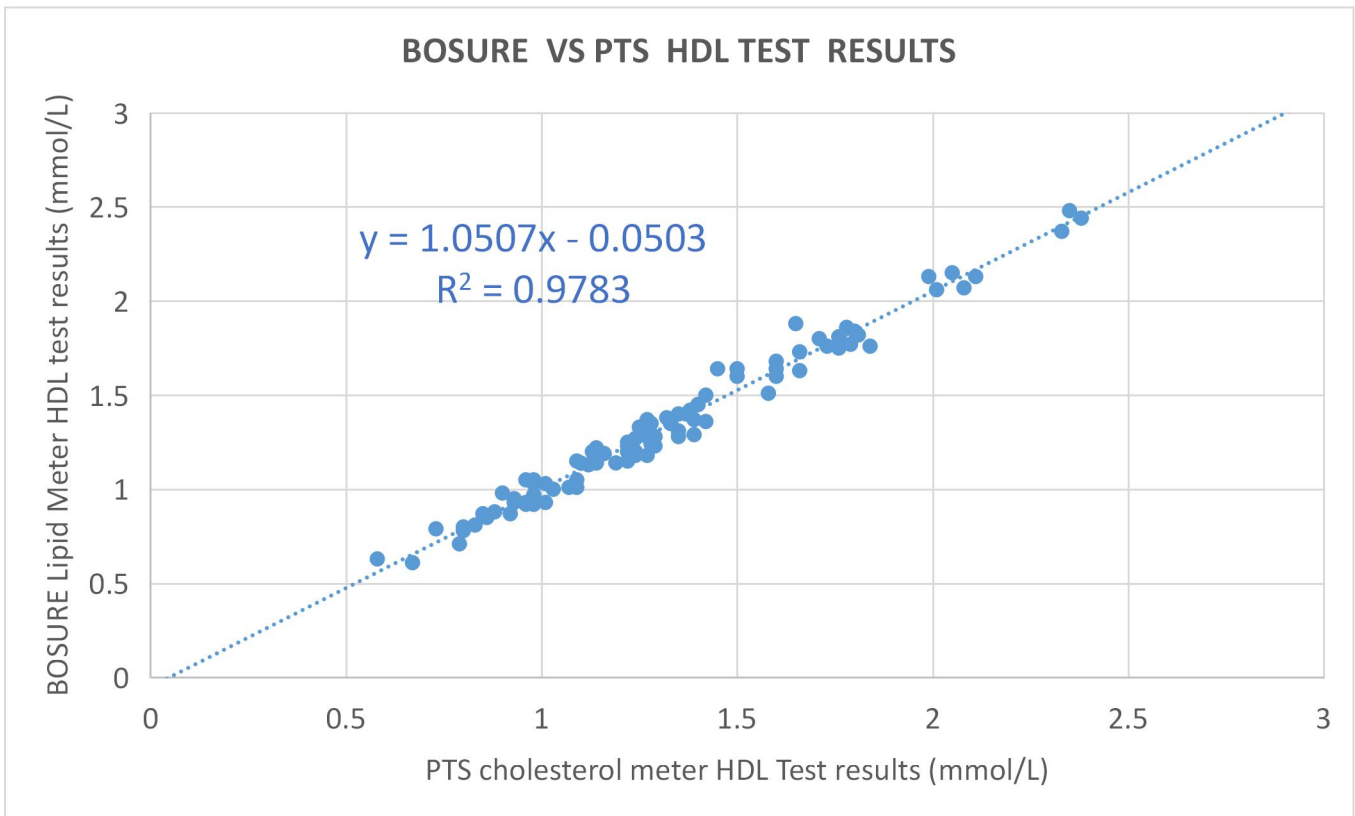
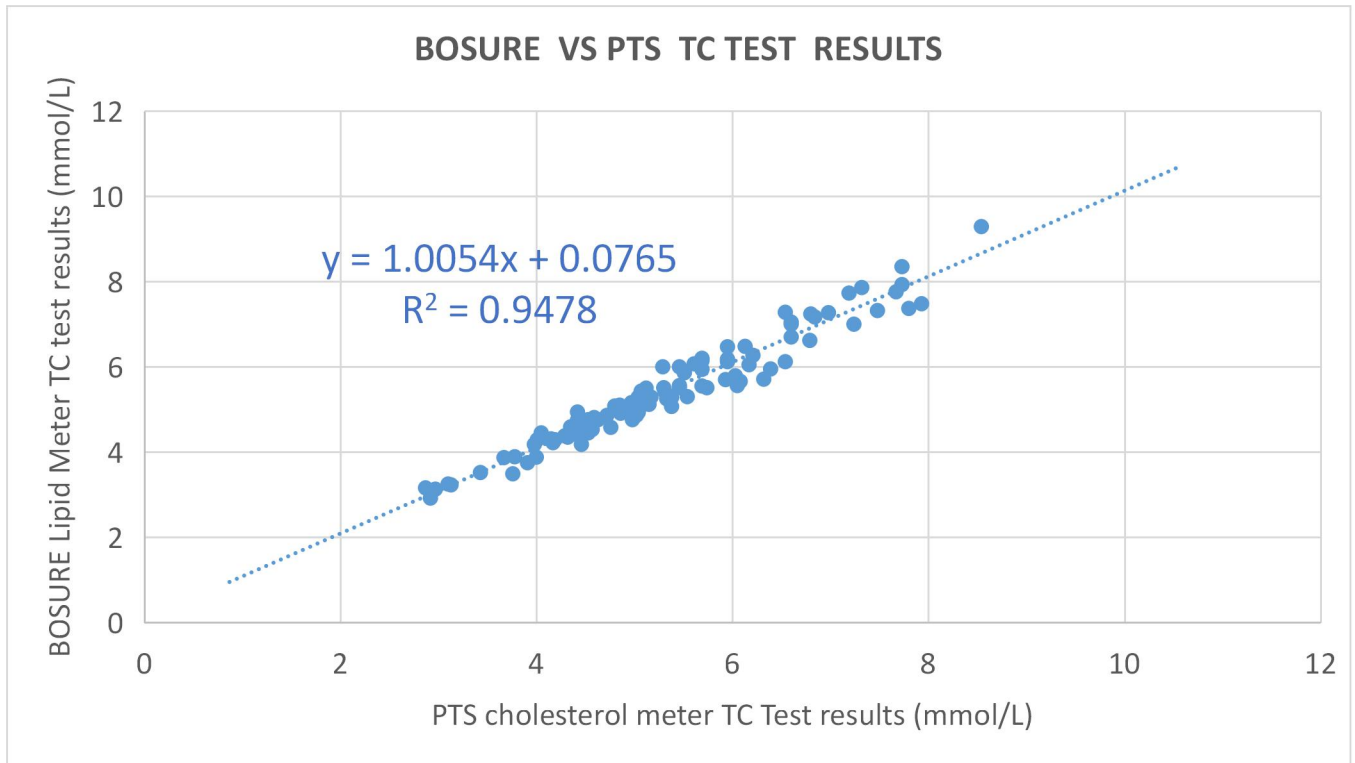
1. Test results

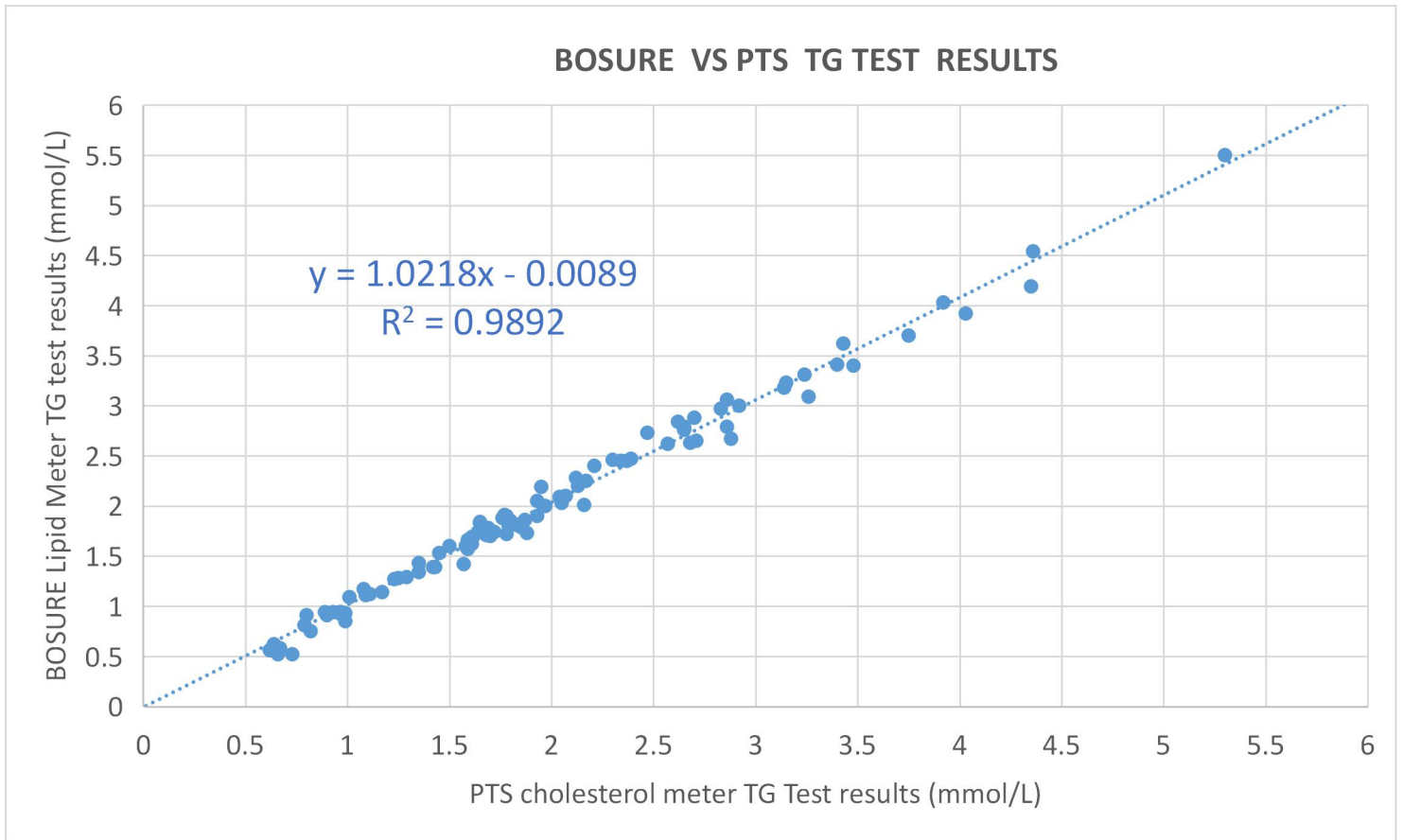
No.	TC (mmol/L)		HDL (mmol/L)		TG (mmol/L)	
	PTS	BOSURE	PTS	BOSURE	PTS	BOSURE
1	5.46	5.56	1.33	1.35	1.57	1.42
2	5.46	5.51	2.05	2.15	0.64	0.62
3	5.04	4.93	1.66	1.63	1.25	1.28
4	6.6	6.7	2.01	2.06	0.79	0.81
5	4.29	4.38	0.98	0.94	1.8	1.85
6	5.51	5.88	1.12	1.13	1.69	1.78
7	5.17	5.29	1.22	1.2	2.04	2.09
8	4.46	4.18	2.08	2.07	0.93	0.94
9	2.92	2.92	0.79	0.71	1.61	1.62
10	4	3.88	1.27	1.18	1.83	1.81
11	4.55	4.66	1.16	1.19	1.65	1.83
12	3.91	3.75	1.37	1.4	1.08	1.17
13	5.54	5.3	1.27	1.28	2.21	2.4
14	7.67	7.76	1.42	1.5	1.64	1.74
15	7.93	7.48	1.35	1.28	3.14	3.18
16	4.57	4.53	1.6	1.6	1.11	1.12
17	6.39	5.95	1.4	1.45	1.72	1.74
18	6.21	6.27	1.84	1.76	1.93	1.9
19	4.32	4.35	1.35	1.31	3.92	4.03
20	3.13	3.23	1.03	1	1.78	1.9
21	5.51	5.86	1.24	1.19	2.71	2.65
22	5.95	6.47	1.22	1.23	1.77	1.91
23	5.69	5.94	1.76	1.75	1.17	1.14
24	6.98	7.27	1.6	1.68	1.42	1.39
25	3.1	3.25	0.83	0.81	0.9	0.91
26	4.01	4.29	1.19	1.14	1.7	1.7
27	4.35	4.59	0.96	0.93	2.83	2.97
28	4.53	4.45	1.38	1.42	2.12	2.28
29	4.19	4.29	1.09	1.15	1.43	1.39
30	4.97	5.1	1.22	1.25	2.3	2.46
31	2.87	3.16	0.98	1.05	1.87	1.86
32	4.98	4.76	0.98	0.97	1.78	1.72
33	5.38	5.07	1.01	0.93	4.03	3.92
34	7.8	7.37	1.32	1.38	5.3	5.5
35	3.76	3.49	1.35	1.4	2.88	2.67
36	6.17	6.05	0.85	0.87	3.48	3.4
37	6.84	7.17	1.29	1.28	1.61	1.67

38	6.79	6.62	1.22	1.2	3.15	3.23
39	6.32	5.71	1.28	1.35	3.24	3.31
40	6.03	5.79	1.45	1.64	0.82	0.75
41	4.76	4.58	0.8	0.8	2.7	2.88
42	4.72	4.86	1.27	1.32	2.65	2.76
43	7.24	7	1.29	1.23	2.86	2.79
44	6.05	5.56	1.14	1.14	2.37	2.45
45	7.73	8.35	0.67	0.61	3.26	3.09
46	5.31	5.42	1.66	1.73	3.4	3.41
47	7.48	7.32	1.71	1.8	1.95	2.19
48	4.86	4.94	1.14	1.14	3.43	3.62
49	5.3	5.51	1.39	1.29	2.16	2.01
50	5.69	6.14	1.24	1.27	0.96	0.93
51	5.95	6.18	1.8	1.84	0.8	0.91
52	5.33	5.25	1.09	1.01	2.62	2.84
53	5.95	6.12	0.8	0.78	1.97	2
54	5.12	5.13	1.58	1.51	2.68	2.63
55	5.07	5.43	2.35	2.48	1.59	1.57
56	5.15	5.12	1.24	1.2	2.17	2.25
57	4.37	4.42	1.07	1.01	1.45	1.53
58	7.73	7.93	1.4	1.45	1.61	1.69
59	5.46	6	1.76	1.81	0.79	0.81
60	2.97	3.13	1.33	1.35	0.99	0.93
61	5.69	5.55	1.6	1.64	0.89	0.94
62	5.93	5.7	1.5	1.64	1.79	1.8
63	6.54	7.28	1.73	1.76	2.47	2.73
64	5.74	5.51	0.98	1.03	2.57	2.62
65	6.6	7.05	2.33	2.37	0.67	0.58
66	7.32	7.86	1.27	1.31	2.86	3.06
67	4.85	5.1	1.28	1.24	1.29	1.29
68	4.96	4.94	1.39	1.37	1.35	1.43
69	3.67	3.87	2.38	2.44	1.93	2.05
70	3.43	3.52	1.25	1.33	0.96	0.94
71	3.98	4.18	1.1	1.14	0.97	0.94
72	4.17	4.22	2.11	2.13	1.88	1.73
73	6.08	5.66	1.79	1.77	1.59	1.66
74	4.05	4.45	1.14	1.19	0.66	0.52
75	4.86	4.91	1.22	1.15	1.65	1.84
76	4.59	4.81	1.24	1.18	1.85	1.79
77	4.56	4.72	0.92	0.87	1.23	1.27
78	5.12	5.5	1.14	1.2	2.92	3
79	4.8	5.08	0.9	0.98	1.61	1.68

80	5.29	6	1.65	1.88	0.99	0.85
81	5.69	6.2	0.88	0.88	2.05	2.03
82	5.04	5.29	0.98	0.92	2.07	2.1
83	4.42	4.75	1.42	1.36	0.73	0.52
84	4.47	4.44	0.93	0.93	4.35	4.19
85	4.97	5.16	0.98	0.96	4.36	4.54
86	5.38	5.28	1.78	1.86	0.62	0.56
87	6.13	6.48	1.99	2.13	1.5	1.6
88	4.63	4.76	1.09	1.05	3.75	3.7
89	7.19	7.73	1.27	1.37	1.58	1.6
90	5.61	6.07	0.96	0.92	1.68	1.71
91	5.02	4.86	1.01	1.03	2.39	2.47
92	4.42	4.94	0.86	0.85	2.65	2.77
93	8.54	9.29	1.81	1.82	1.35	1.34
94	6.54	6.12	1.14	1.22	2.13	2.2
95	4.53	4.76	0.73	0.79	2.65	2.79
96	6.6	7	1.5	1.6	1.76	1.88
97	6.8	7.24	0.96	1.05	1.09	1.11
98	3.78	3.89	0.58	0.63	2.34	2.45
99	4.15	4.31	1.13	1.2	1.66	1.78
100	4.54	4.74	0.93	0.95	1.01	1.09

2. Data Analysis





Summary of correlation study:

TC Test Result	HDL Test Result	TG Test Result
$y = 1.0054x + 0.0765$	$y = 1.0507x - 0.0503$	$y = 1.0218x - 0.0089$
$R^2 = 0.9478$	$R^2 = 0.9783$	$R^2 = 0.9892$
$r = 0.9736$	$r = 0.9890$	$r = 0.9946$

Conclusion:

BOSURE Lipid Testing System has good correlation comparing with the market leader product of PTS Cholesterol test system.