Hb pro Hemoglobin Testing System

Clinical Comparison Study

Report No. B0028-04-05-02-07 Version 1.0

Purpose：

The purpose of this study was to compare Hb pro Hemoglobin Testing System with Hemocue 301 Analyzer.

Materials:

Hb pro Hemoglobin Microcuvettes: HB24120103
Hb pro Hemoglobin Meter SN No.: 12020000022
Hemocue Hb 301 analyzer SN No.: 2245821793
Hemocue Hb 301 Hemoglobin Microcuvettes: 2408444

Methods:

100 Venous whole blood specimens with EDTA-K2 anticoagulant was collected from volunteers. Because specimens with low and high concentrations are difficult to obtain. Some low and high concentration specimens were obtained by adjusting the plasma volume in the specimen. Gently mix the specimen for at least 15 minutes before testing. To avoid blood lysis, do not stir the specimen excessively or mix the specimen for too long. Each specimen is tested using two methods: Hb pro hemoglobin testing system and Hemocue Hb 301 analyzer.
Fingertip blood specimens were collected from volunteers after drawing venous blood right now, not more than 20 minutes. The fingertip blood was also tested by Hb pro hemoglobin testing system and Hemocue Hb 301 analyzer.Compare the test results of both methods.

Accepted Criteria:
The correlation coefficient expressed as (r) should be not less than 0.975.
The Bias% at medical decision point is not more than 4%.

Results:

Sample	Hb pro Hemoglobin testing system		Hemocue 301	
	Venous y_1 g/dL	Fingertip y_2 g/dL	Venous x_1 g/dL	Fingertip x_2 g/dL
1	13.5	13.4	13.4	13.4
2	20.3	20.2	20.0	20.0
3	8.9	9.7	9.0	9.5
4	7.7	7.9	8.1	7.9
5	15.6	15.4	15.1	15.9
6	6.1	6.6	6.1	6.1
7	17.7	17.7	17.6	17.4
8	14.7	15.3	15.1	14.7
9	11.4	10.9	11.2	10.9
10	19.0	19.4	18.8	18.9
11	6.6	6.3	6.7	6.6
12	11.7	11.3	11.4	11.3
13	13.3	13.3	12.9	13.0
14	11.7	12.4	11.6	12.0
15	9.7	10.2	9.8	9.9
16	12.1	11.9	12.1	12.3
17	12.8	12.4	12.3	12.9
18	5.1	5.2	5.7	5.7
19	6.2	7.0	6.9	6.2
20	17.1	16.9	17.0	17.1
21	13.8	13.7	13.8	13.4
22	11.4	10.7	11.3	11.1
23	9.0	8.3	8.5	9.1
24	7.1	7.7	7.1	7.6
25	14.3	14.3	14.3	13.6
26	11.0	10.9	10.4	10.3
27	5.6	5.6	6.3	6.3
28	8.0	7.6	8.0	7.8
29	6.9	6.2	6.5	6.9
30	8.6	8.6	9.3	9.0
31	15.4	15.4	16.0	15.3
32	16.9	16.7	16.9	16.6
33	15.9	15.7	16.1	15.9
34	7.9	7.6	8.1	7.6
35	16.0	15.6	15.8	15.7
36	17.0	17.4	16.9	16.6
37	11.2	11.8	11.2	11.1
38	17.8	17.8	17.7	18.2
39	7.0	6.9	7.2	6.8

Sample	Hb pro Hemoglobin testing system		Hemocue 301	
	Venous y_1 g/dL	Fingertip y_2 g/dL	Venous x_1 g/dL	Fingertip x_2 g/dL
40	19.1	19.0	18.9	18.9
41	4.1	4.2	4.2	4.6
42	14.1	14.1	13.6	13.4
43	5.1	5.2	4.7	4.9
44	13.5	13.3	13.3	13.4
45	14.2	13.7	14.0	13.7
46	12.9	13.1	12.4	13.1
47	16.5	16.4	16.1	16.2
48	18.6	18.2	18.1	18.0
49	9.3	9.1	9.6	9.0
50	9.4	9.4	9.0	9.0
51	9.5	9.3	8.9	9.0
52	13.8	13.5	13.5	14.2
53	16.0	15.9	16.6	16.6
54	14.5	14.4	14.9	14.5
55	12.9	13.0	13.3	13.1
56	14.6	15.1	14.8	14.8
57	6.5	6.4	5.9	6.3
58	5.9	5.7	5.7	5.5
59	17.6	17.0	17.5	17.2
60	11.1	10.9	11.2	11.3
61	10.9	11.3	11.1	11.2
62	19.2	18.8	19.4	19.5
63	11.2	11.0	11.5	11.3
64	15.0	15.1	14.3	14.8
65	18.8	18.6	19.3	18.9
66	7.9	8.2	7.9	8.0
67	6.5	5.9	5.8	6.4
68	7.5	8.3	8.2	8.3
69	11.0	11.0	10.7	10.3
70	17.3	17.0	16.8	17.1
71	17.5	16.8	17.1	17.5
72	18.0	17.8	18.2	18.2
73	6.3	6.8	6.6	6.6
74	3.8	4.5	4.1	4.1
75	14.2	14.7	14.5	14.3
76	17.6	17.9	18.3	18.0
77	16.5	16.5	16.2	15.9
78	13.6	13.5	13.4	13.6

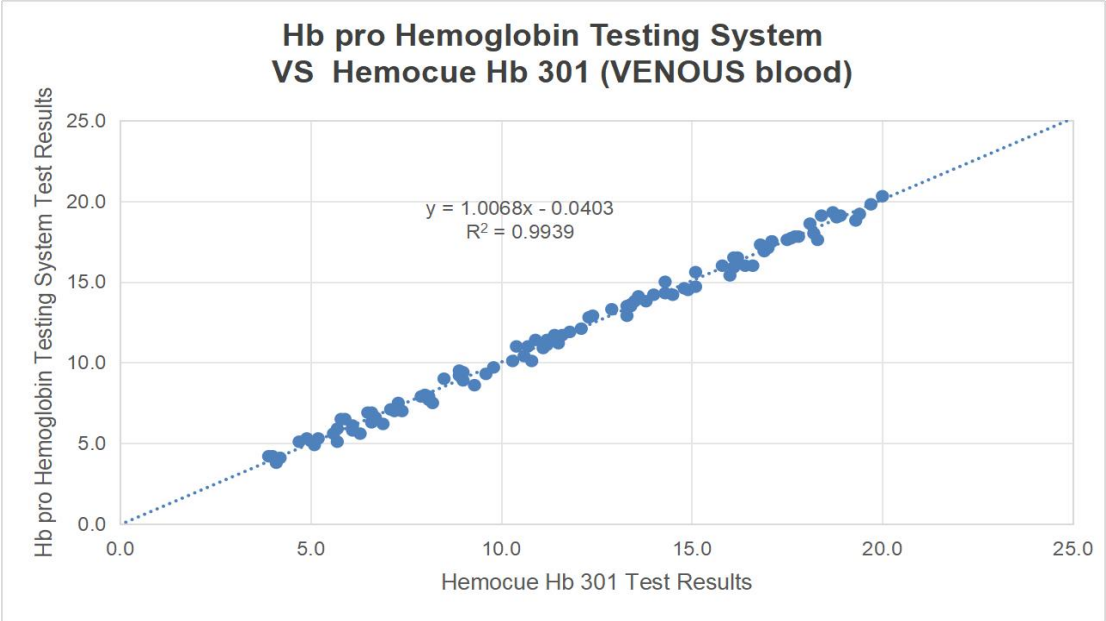
Sample	Hb pro Hemoglobin testing system		Hemocue 301	
	Venous y_1 g/dL	Fingertip y_2 g/dL	Venous x_1 g/dL	Fingertip x_2 g/dL
79	4.2	4.3	3.9	3.6
80	17.5	17.5	17.1	17.3
81	19.8	19.7	19.7	20.1
82	7.0	7.0	7.4	7.1
83	19.1	18.4	18.4	18.8
84	5.6	5.3	5.6	5.9
85	5.3	5.3	4.9	4.7
86	10.1	9.6	10.3	9.8
87	11.9	12.0	11.8	12.5
88	7.5	7.6	7.3	7.7
89	11.4	11.0	10.9	11.1
90	10.4	10.5	10.6	10.8
91	19.3	18.9	18.7	18.9
92	10.1	10.9	10.8	10.4
93	4.9	4.5	5.1	4.6
94	4.2	3.7	4.0	3.6
95	16.0	16.3	16.4	15.9
96	17.8	18.2	17.8	18.0
97	6.9	6.7	6.6	6.9
98	9.2	9.2	8.9	8.8
99	5.8	5.9	6.1	6.0
100	5.3	5.5	5.2	5.5

DATA ASSAY

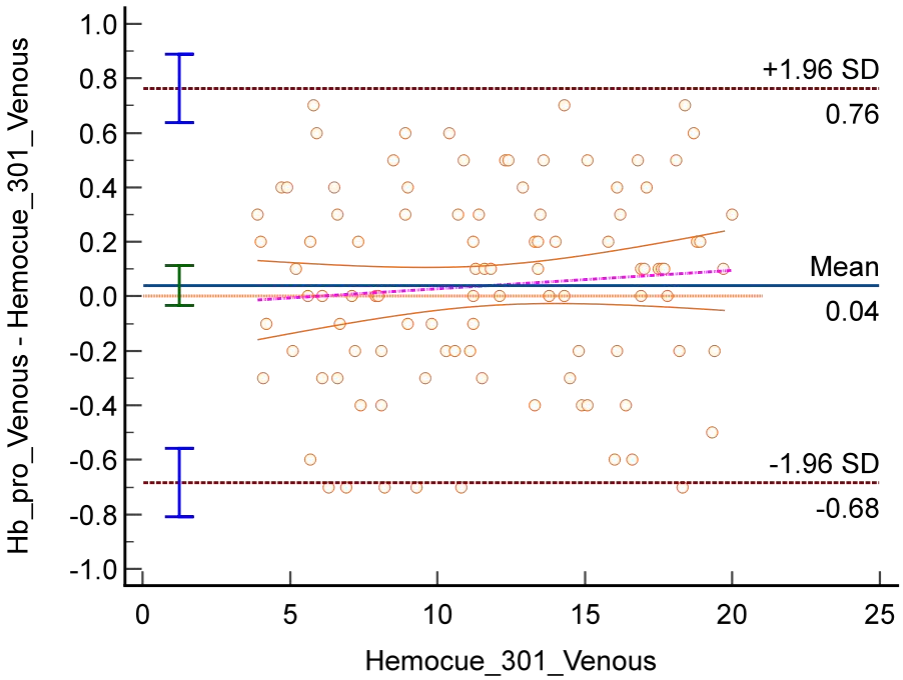
1) Compare Venous blood test results

Sample size	100
Min Results(g/dL)	3.9
Max Results(g/dL)	20.0
Mean Results (g/dL)	11.8
Mean difference (g/dL)	0.04
SD(g/dL)	0.37
Mean difference (%)	0.3%
SD(%)	4.2%
Arithmetic mean	0.04000
95% Confidence interval	-0.03322 to 0.1132
P (H0: Mean=0)	0.2810
Lower limit	-0.6832
95% Confidence interval	-0.8088 to -0.5577
Upper limit	0.7632
95% Confidence interval	0.6377 to 0.8888
Intercept	-0.04
Slope	1.0068
r	0.9969
Accepted Criteria	r≥0.975
PASS/FAIL	PASS

Medical Decision Level 1 (Xc g/dL)	10.0
Estimate of the predicted bias (Bc g/dL)	0.03
Estimate of the predicted bias% (Bc%)	0.3%
Medical Decision Level 2 (Xc g/dL)	13.0
Estimate of the predicted bias (Bc g/dL)	0.05
Estimate of the predicted bias% (Bc%)	0.4%
Accepted Criteria	Bc%≤±4%
PASS/FAIL	PASS



Pic 1 Correlation Assay of Venous blood test results

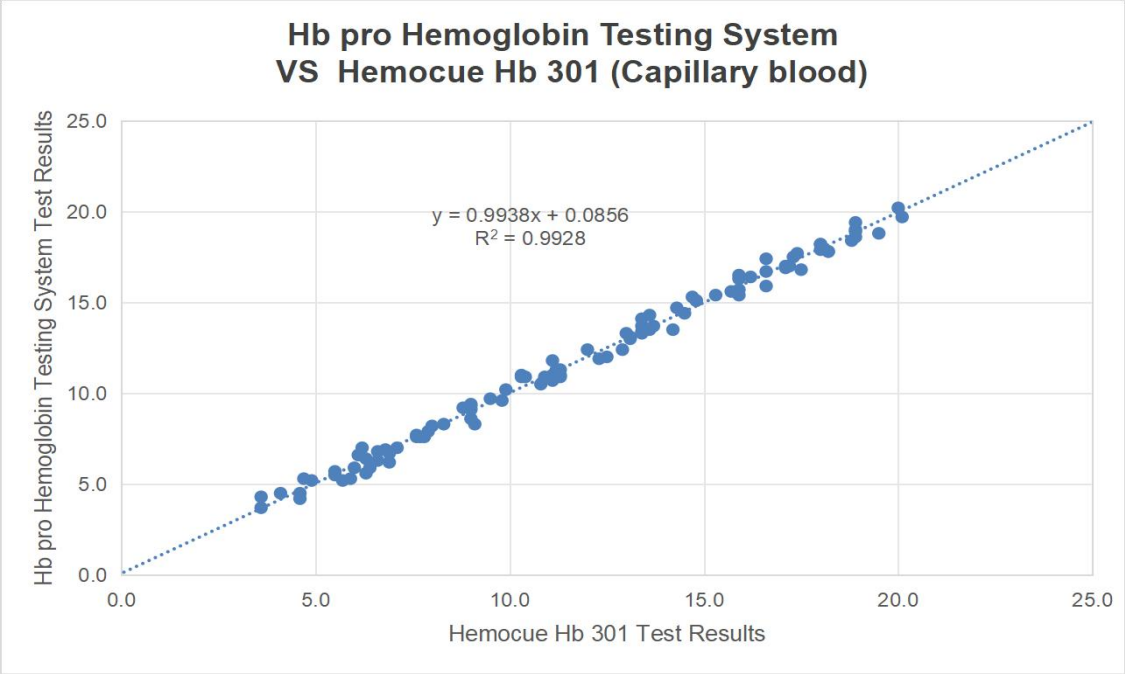


Pic 2 Bland-Altman Plot of Venous blood test results

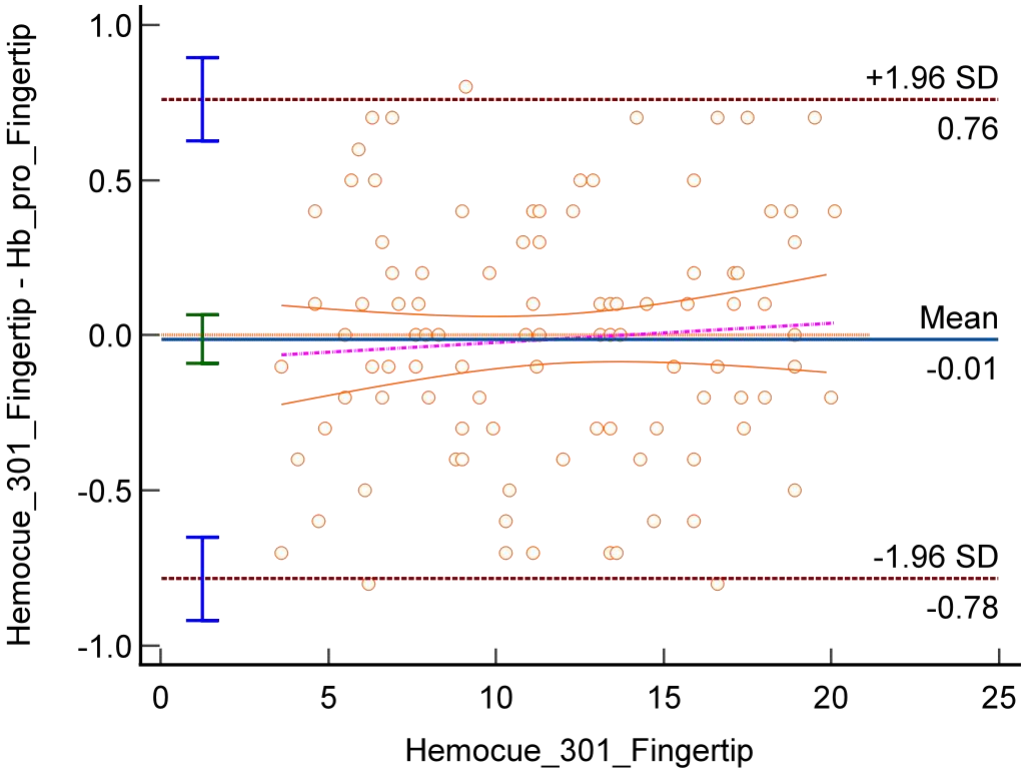
2) Compare Capillary blood test results

Sample size	100
Min Results(g/dL)	3.6
Max Results(g/dL)	20.1
Mean Results (g/dL)	11.8
Mean difference (g/dL)	0.01
SD(g/dL)	0.39
Mean difference (%)	0.3%
SD(%)	4.7%
Arithmetic mean	-0.01200
95% Confidence interval	-0.09022 to 0.06622
P (H0: Mean=0)	0.7615
Lower limit	-0.7847
95% Confidence interval	-0.9188 to -0.6505
Upper limit	0.7607
95% Confidence interval	0.6265 to 0.8948
Intercept	0.0856
Slope	0.9938
r	0.9964
Accepted Criteria	r≥0.975
PASS/FAIL	PASS

Medical Decision Level 1 (Xc g/dL)	10.0
Estimate of the predicted bias (Bc g/dL)	0.02
Estimate of the predicted bias% (Bc%)	0.2%
Medical Decision Level 2 (Xc g/dL)	13.0
Estimate of the predicted bias (Bc g/dL)	0.00
Estimate of the predicted bias% (Bc%)	0.0%
Accepted Criteria	Bc%≤±4%
PASS/FAIL	PASS



Pic 3 Correlation Assay of Venous blood test results



Pic 4 Bland-Altman Plot of Capillary blood test results

CONCLUSION

According to the compare test results, the Hb pro testing system give consistence results with Hemocue Hb 301 analyzer.