

**Study Result QCT342: The Accuracy and User
Performance Evaluation of GAL-1C Blood Glucose
Monitoring System**

Test Date: 2011/01/14 - 2011/01/27

Site: SCHMIDT Group Practice Clinic
No. 29, Chung-shan Rd., Hsinchu, Taiwan, ROC
Tel: 03-5277333 Fax: 03-5277889

Principle Investigator: Fu-Hsiang Chen Date: 2011/3/18

Co-investigator: May-Tze Lee Date: 2011/3/18

Co-investigator: Lih-Mei Chen Date: 2011/3/18

1. MATERIALS and EQUIPMENTS INFORMATION

- 1.1 GAL-1C Meters: 8 meters, S/N AN000041 – 48.
- 1.2 GAL-1C Test Strip: three (3) lots, 10 bottles per lot, Lot No. TMS500A, TMS500B and TMS500C.
- 1.3 Contrex Plus III Control Solution: one lot, each 30 bottles of Level 1 and Level 2, Lot No. TAC990701M for the Level 1 and TAC990701H for the Level 2.
- 1.4 YSI-2300 Glucose Analyzer: Equipment No. 130308, calibrated each day before use.
- 1.5 The Lot No. and expired date of YSI control materials:
 - 0 mg/dL: 09A101691, Feb-2012
 - 180 mg/dL: 10J101003, Oct-2011
 - 500 mg/dL: 10F100407, Jun-2011
- 1.6 YSI linearity control check solution: NERL1343 Standard Glucose Solution: glucose concentration of 50, 100, 200, 400, 750 mg/dL, Lot No. 03280230, Expired at Mar-2012.
- 1.7 Heparinized blood collection tubes for capillary blood collection: approximate 320 Capi-ject, manufactured by Microvette CB300 LH, SARTEDT, Germany.
- 1.8 Beckman Microfuge Lite centrifuge: Equipment No. 120004, calibrated at 2010/8/31.
- 1.9 Thermometer/Hygrometer: Equipment No. 140418, calibrated at 2010/9/6.
- 1.10 Lancing device and sterilized lancet: 160 lancing device and 320 sterilized lancets, manufactured by Jinan Lianfa Medical Plastic Products Co. Ltd, China, Lot No. 01-100948, expired at Aug-2015.
- 1.11 Sterile single use lancet: approximate 320 Tenderlett lancets, manufactured by ITC, USA, Lot No. NH809, Expiry Jun-2012.
- 1.12 EPA certified disinfectant towel: EPA No. 56392-8, 600 wipes total, Lot No. DC101001, Expired at Jul-2011.

1.13 Glucose stock solution (25%) in 0.9% saline: 1 tube of 0.3mL, prepared by ApexBio, Lot No. 990906, Expired at Dec-2011.

2. SUBJECT INFORMATION

2.1 Subjects and Test Samples:

2.1.1 Total of 150 valid participants have signed the Informed Consent and fill the Subject Information to joint to the test. There are 5 subjects refused to take additional sticks to complete all tests, therefore the resulted valid tests number are 145.

2.1.2 The age distribution is 15 - 74 years old and the sex percentages are around 50% to 50%, education levels are junior high school to post graduate, 93 diabetics are included in test. The subjects information are summarized as below.

Table of subject information:

Age	<21	21 – 30	31 – 40	41 – 50	51 – 60	61 – 70	>70
No.	4	35	40	16	15	29	6
Sex	Male	Female					
No.	75	70					
Education Level	Non or some high school	High school	College or Technical school	4-year College	Graduate degree		
No.	4	42	15	34	50		
Diabetes type	Type 1	Type 2	Gestational				
No..	14	75	4				

3. GLUCOSE DISTRIBUTION

3.1 Except the 145 fresh capillary bloods, there are additional 7 glucose hydrolysis blood samples collected from participants' fingertip were tested to result total of 152 valid data by the professional, cover the glucose level from 34 mg/dL to 519 mg/dL.

3.2 The glucose ranges and distributions are summarized as the following table, which met the required percentages as section 7.3.1.2 of ISO 15197.

Table of glucose range and distribution:

Glucose level (mg/dL)	Designated sample number	Professional's finger test	
		Sample number	Percentage of sample (%)
Glucose range	--	34 – 519 mg/dL	
<50	7-8	6	3.9%
50 to 80	22-23	24	15.8%
81 to 120	30	30	19.7%
121 to 200	45	46	30.3%
201 to 300	22-23	23	15.1%
301 to 400	15	15	9.9%
>400	7-8	8	5.3%
Total	150	152	100%

4 TEST RESULT

4.1 Test Raw Data

4.1.1 Total of 145 fresh fingertip capillary samples and 7 glucose hydrolysis samples were tested. The professional tested for all the 152 samples, the users tested for the 145 fresh samples.

4.1.2 3 strip lots were used to test the 152 samples, by 49, 54 and 49 samples of each individual lot.

4.1.3 Raw data of all tests are summarized as the **APPENDIX 1**.

4.2 Accuracy Evaluation

4.2.1 152 samples, 145 fresh samples and 7 glucose hydrolysis samples, from fingertip tested by the healthcare professional are collected for the system accuracy evaluation.

4.2.2 Regression Analysis

Per section 7.3.3.3 of ISO 15197, the linear regression of the GAL-1C meter against the YSI, tested by healthcare professional of 3 strip lots

combined are analyzed and the results are detailed as **EXHIBIT 1 at APPENDIX 2**.

- The R square from tests of total 152 samples is 0.985.

4.2.3 Bias analysis and the Minimum System Accuracy

Per section 7.4.1 of ISO 15197, the bias of the GAL-1C meter to YSI, tested by healthcare professional of 3 strip lots combined are analyzed and the results are detailed as **EXHIBIT 2 at APPENDIX 2**.

- Total of 99% (151/152) fall in the acceptance criteria as +/-15mg/dL at glucose <75 mg/dL and +/-15% at glucose \geq 75 mg/dL, met the minimum accuracy requirement at this evaluation.

4.3 User Performance

4.3.1 145 fresh capillary samples from fingertip, palm and forearm tested by the lay users are collected for the user performance evaluation.

4.3.2 Regression Analysis

The linear regression of GAL-1C meter against the YSI, tested by users of 3 strip lots combined are analyzed and the results are detailed as **EXHIBIT 1 at APPENDIX 3**.

- The r square from total 145 tests is 0.983, 0.982 and 0.982 for the user tests of fingertip, palm and forearm, respectively.

4.3.3 Bias analysis and the minimum accuracy of system

The bias of the GAL-1C meter to YSI, tested by the users of 3 strip lots combined are analyzed and the results are detailed as **EXHIBIT 2 at APPENDIX 2**.

- Total of 99% (144/145), 100% (145/145) and 99% fall in the acceptance criteria as +/-15mg/dL at glucose <75 mg/dL and +/-20% at glucose \geq 75 mg/dL, met requirement for the user test at this evaluation.

4.3.4 Tests of Control Solution

The test results of control solution are compared to the acceptable ranges in the label of strip bottle to count the percentages of accurate control test.

- The accurate tests are 99% (144/145) for Level 1 and 99% (143/145) for Level 2. Most the users can perform the control solution tests accurately.

5 CONCLUSION

According to the study protocol, as compared to the reference method YSI 2300 analyzer, the GAL-1C Blood Glucose Monitoring System shows the acceptable accuracy and user performance, met the acceptance criteria.

APPENDIX 1: RAW DATA

Study Result QCT342: The Accuracy and User Performance
Evaluation of GAL-1C Blood Glucose Monitoring System

RAW DATA of GAL-1C CLINICAL TEST:

Sample ID	YSI-1st	YSI-2nd	YSI-Mean	Professional finger	User finger	User palm	User forearm	Test date	Strip lot
1	176	177	177	171	172	173	169	1-14	TMS500A
2	166	164	165	155	152	163	162	1-14	TMS500A
3	522	516	519	479	496	506	473	1-14	TMS500A
4	87.0	87.0	87	84	78	76	78	1-14	TMS500A
5	227	226	227	225	230	227	230	1-14	TMS500A
6	252	254	253	226	240	234	234	1-14	TMS500A
7	333	333	333	351	345	359	344	1-14	TMS500A
8	169	168	169	174	165	165	163	1-14	TMS500A
9	66.5	65.6	66	71	64	74	64	1-14	TMS500A
10	283	283	283	266	273	264	281	1-14	TMS500A
11	196	198	197	187	177	182	165	1-14	TMS500A
12	423	422	423	445	397	431	435	1-14	TMS500A
13	90.0	89.2	90	97	95	100	102	1-14	TMS500A
14	231	230	231	251	249	246	242	1-17	TMS500B
15	68.7	69.2	69	63	73	63	68	1-17	TMS500B
16	95.0	94.5	95	87	88	90	85	1-17	TMS500B
17	80.2	79.0	80	83	82	83	76	1-17	TMS500B
18	115	114	115	106	104	102	99	1-17	TMS500B
19	149	148	149	146	147	148	143	1-17	TMS500B
20	95.5	94.2	95	82	85	77	84	1-17	TMS500B
21	296	295	296	297	307	311	301	1-17	TMS500B
22	147	146	147	130	142	134	128	1-17	TMS500B
23	308	308	308	320	327	326	317	1-17	TMS500B
24	290	289	290	324	326	314	343	1-17	TMS500B
25	132	131	132	128	123	118	121	1-18	TMS500C
26	353	354	354	337	336	329	342	1-18	TMS500C
27	160	161	161	149	148	153	152	1-18	TMS500C
28	277	278	278	292	280	278	292	1-18	TMS500C
29	417	418	418	393	441	425	396	1-18	TMS500C
30	192	191	192	210	199	197	188	1-18	TMS500C
31	73.0	73.3	73	73	63	64	67	1-18	TMS500C
32	92.6	90.2	91	97	102	103	107	1-18	TMS500C
33	96.1	95.0	96	94	91	94	86	1-18	TMS500C
34	91.0	89.6	90	92	87	80	85	1-18	TMS500C
35	152	149	151	170	172	167	170	1-18	TMS500C
36	64.9	65.1	65	63	72	65	61	1-18	TMS500C
37	192	192	192	184	195	188	190	1-18	TMS500C
38	292	291	292	293	285	315	308	1-18	TMS500C
39	464	461	463	488	440	452	441	1-18	TMS500C
40	62.5	64.0	63	63	61	66	64	1-19	TMS500A
41	155	154	155	150	147	156	147	1-19	TMS500A

Study Result QCT342: The Accuracy and User Performance
Evaluation of GAL-1C Blood Glucose Monitoring System

Page: 9 of 20

Sample ID	YSI-1st	YSI-2nd	YSI-Mean	Professional finger	User finger	User palm	User forearm	Test date	Strip lot
42	119	119	119	111	113	113	108	1-19	TMS500A
43	85.0	85.0	85	83	86	95	95	1-19	TMS500A
44	72.3	71.4	72	76	70	69	70	1-19	TMS500A
45	141	140	141	141	137	150	158	1-19	TMS500A
46	339	338	339	347	354	360	375	1-19	TMS500A
47	125	124	125	128	128	129	127	1-19	TMS500A
48	251	251	251	259	254	273	243	1-19	TMS500A
49	122	121	122	125	119	122	131	1-19	TMS500A
50	118	117	118	112	114	113	103	1-19	TMS500A
51	309	309	309	303	290	307	299	1-20	TMS500B
52	69.2	67.8	69	66	70	70	63	1-20	TMS500B
53	178	178	178	184	180	174	178	1-20	TMS500B
54	189	189	189	206	187	196	192	1-20	TMS500B
55	407	406	407	404	419	427	438	1-20	TMS500B
56	135	133	134	128	124	127	119	1-20	TMS500B
57	331	331	331	342	325	371	340	1-20	TMS500B
58	150	149	150	140	142	148	141	1-20	TMS500B
59	378	379	379	449	438	447	420	1-20	TMS500B
60	341	341	341	350	361	343	331	1-20	TMS500B
61	307	306	307	296	303	298	309	1-21	TMS500C
62	111	110	111	103	115	104	112	1-21	TMS500C
63	182	180	181	200	212	215	214	1-21	TMS500C
64	283	282	283	272	273	265	262	1-21	TMS500C
65	158	155	157	171	164	158	156	1-21	TMS500C
66	92.7	91.6	92	94	99	88	86	1-21	TMS500C
67	73.5	74.6	74	69	63	66	67	1-21	TMS500C
68	131	130	131	126	126	120	130	1-21	TMS500C
69	82.4	81.7	82	79	75	76	76	1-21	TMS500C
70	443	444	444	441	407	404	420	1-22	TMS500A
71	183	181	182	160	167	176	161	1-22	TMS500A
72	85.0	85.8	85	79	82	78	66	1-22	TMS500A
73	66.5	64.0	65	59	68	60	59	1-22	TMS500A
74	299	298	299	280	277	292	278	1-22	TMS500A
75	320	319	320	325	317	329	351	1-22	TMS500A
76	188	188	188	180	181	172	181	1-22	TMS500A
77	186	187	187	182	183	181	182	1-22	TMS500A
78	154	154	154	155	143	146	146	1-22	TMS500A
80	273	272	273	270	252	263	260	1-22	TMS500A
81	128	127	128	121	115	114	119	1-22	TMS500A
83	92.0	92.6	92	90	88	85	87	1-22	TMS500A
84	258	257	258	230	221	229	238	1-22	TMS500A
85	327	324	326	302	303	305	294	1-23	TMS500B

Study Result QCT342: The Accuracy and User Performance
Evaluation of GAL-1C Blood Glucose Monitoring System

Page: 10 of 20

Sample ID	YSI-1st	YSI-2nd	YSI-Mean	Professional finger	User finger	User palm	User forearm	Test date	Strip lot
86	142	144	143	140	127	140	135	1-23	TMS500B
87	213	212	213	193	187	201	210	1-23	TMS500B
89	138	139	139	141	135	132	141	1-23	TMS500B
90	271	270	271	282	272	271	278	1-23	TMS500B
91	348	348	348	325	312	313	324	1-23	TMS500B
92	260	261	261	263	247	258	264	1-23	TMS500B
93	146	144	145	143	149	146	154	1-23	TMS500B
94	159	160	160	147	140	141	151	1-23	TMS500B
95	239	239	239	220	221	209	218	1-23	TMS500B
96	156	155	156	149	140	140	149	1-23	TMS500B
97	186	188	187	180	173	179	185	1-23	TMS500B
98	399	398	399	366	385	372	391	1-23	TMS500B
99	71.1	70.4	71	60	65	65	73	1-23	TMS500B
100	420	419	420	424	421	422	449	1-23	TMS500B
102	213	213	213	208	203	202	200	1-23	TMS500B
103	247	245	246	259	267	256	252	1-23	TMS500B
104	303	302	303	292	286	290	303	1-23	TMS500B
105	202	200	201	205	213	205	214	1-23	TMS500B
106	182	182	182	197	195	188	186	1-23	TMS500B
107	162	161	162	145	148	148	149	1-23	TMS500B
108	401	404	403	358	361	375	367	1-23	TMS500B
109	238	238	238	243	241	249	247	1-23	TMS500B
110	97.0	97.0	97	95	97	99	98	1-24	TMS500C
111	62.0	62.0	62	60	56	62	59	1-24	TMS500C
112	86.0	87.0	87	90	84	82	84	1-24	TMS500C
113	142	143	143	149	155	149	154	1-24	TMS500C
114	100	100	100	94	93	96	96	1-24	TMS500C
115	136	136	136	122	138	138	127	1-24	TMS500C
116	68.0	67.0	68	69	77	63	61	1-24	TMS500C
117	62.0	61.0	62	66	53	59	56	1-24	TMS500C
118	69.0	69.0	69	66	69	57	66	1-24	TMS500C
119	137	138	138	142	146	127	135	1-24	TMS500C
120	180	181	181	171	162	166	164	1-24	TMS500C
121	107	108	108	103	105	97	104	1-24	TMS500C
122	219	219	219	201	203	196	206	1-24	TMS500C
123	187	187	187	179	177	218	178	1-24	TMS500C
124	172	171	172	162	164	163	152	1-24	TMS500C
125	245	244	245	245	222	226	218	1-24	TMS500C
126	88.0	88.0	88	87	77	85	83	1-25	TMS500A
128	130	129	130	120	130	130	123	1-25	TMS500A
129	68.0	67.0	68	60	55	58	57	1-25	TMS500A
130	91.0	90.0	91	86	93	98	93	1-25	TMS500A

Study Result QCT342: The Accuracy and User Performance
Evaluation of GAL-1C Blood Glucose Monitoring System

Page: 11 of 20

Sample ID	YSI-1st	YSI-2nd	YSI-Mean	Professional finger	User finger	User palm	User forearm	Test date	Strip lot
131	75.0	75.0	75	82	79	79	83	1-25	TMS500A
132	66.0	66.0	66	72	68	71	66	1-25	TMS500A
133	95.0	95.0	95	93	94	93	96	1-25	TMS500A
134	126	126	126	117	122	125	117	1-25	TMS500A
135	92.0	92.0	92	89	90	83	93	1-25	TMS500A
136	127	126	127	119	108	113	118	1-25	TMS500A
137	84.0	84.0	84	81	83	89	83	1-26	TMS500B
138	61.0	59.0	60	62	58	63	63	1-26	TMS500B
139	102	101	102	108	108	106	104	1-26	TMS500B
140	326	326	326	304	310	278	309	1-26	TMS500B
141	112	111	112	104	99	100	102	1-26	TMS500B
142	106	103	105	104	114	112	102	1-26	TMS500B
143	119	120	120	115	108	109	113	1-26	TMS500B
144	73.0	73.0	73	73	69	67	61	1-26	TMS500B
145	124	123	124	125	122	119	120	1-27	TMS500C
146	70.0	69.0	70	75	76	60	68	1-27	TMS500C
147	125	124	125	126	128	125	130	1-27	TMS500C
148	116	117	117	122	112	115	123	1-27	TMS500C
149	66.0	66.0	66	71	59	59	62	1-27	TMS500C
150	73.0	72.0	73	83	81	83	79	1-27	TMS500C
(44)*	33.6	34.2	34	33	--	--	--	1-19	TMS500A
(52)*	40.8	42.5	42	52	--	--	--	1-20	TMS500B
(73)*	42.4	46.7	45	42	--	--	--	1-22	TMS500A
(99)*	54.3	54.2	54	51	--	--	--	1-23	TMS500B
(116)*	47.2	47.9	48	43	--	--	--	1-24	TMS500C
(117)*	48.1	45.6	47	42	--	--	--	1-24	TMS500C
(146)*	46.5	47.2	47	48	--	--	--	1-27	TMS500C

*: The glucose hydrolysis samples.

Sample ID **(44)** means the blood is collected from sample ID 44.

APPENDIX 2: ACCURACY

Exhibit 1: Regression Analysis

A. Regression data

Sample numbers	Glucose concentration (mg/dL)	R ² value	Slope
152	34 – 519	0.985	0.992

B. Scatter Plots

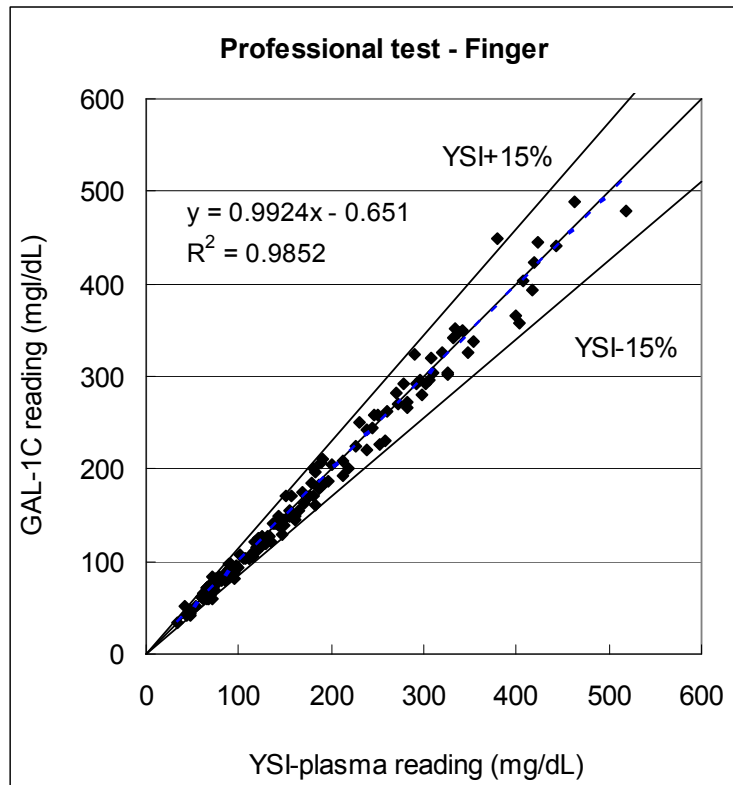


Exhibit 2: Bias Analysis

A. Bias Distribution

for blood glucose <75 mg/dL:

Bias range	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
N in total (%)	19/28 (68%)	25/28 (89%)	28/28 (100%)

for blood glucose ≥ 75 mg/dL

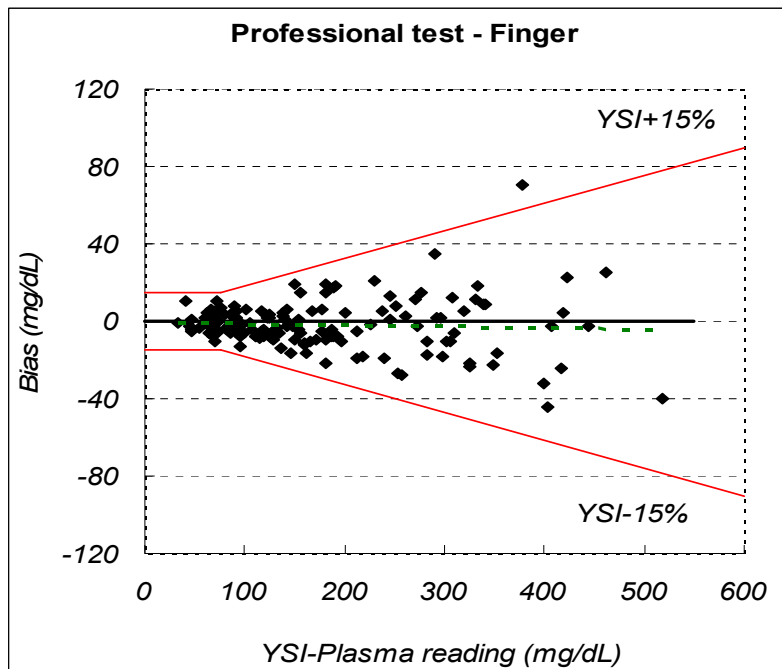
Bias range	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
N in total (%)	69/124 (56%)	112/124 (90%)	123/124 (99%)	124/124 (100%)

for total samples

Total within criteria
151/152 (99%)

Acceptance criteria of professional test: 95% within $\pm 15\%$ or ± 15 mg/dL for glucose level ≥ 75 mg/dL or < 75mg/dL, respectively

B. Bias Plot



APPENDIX 3: USER PERFORMANCE

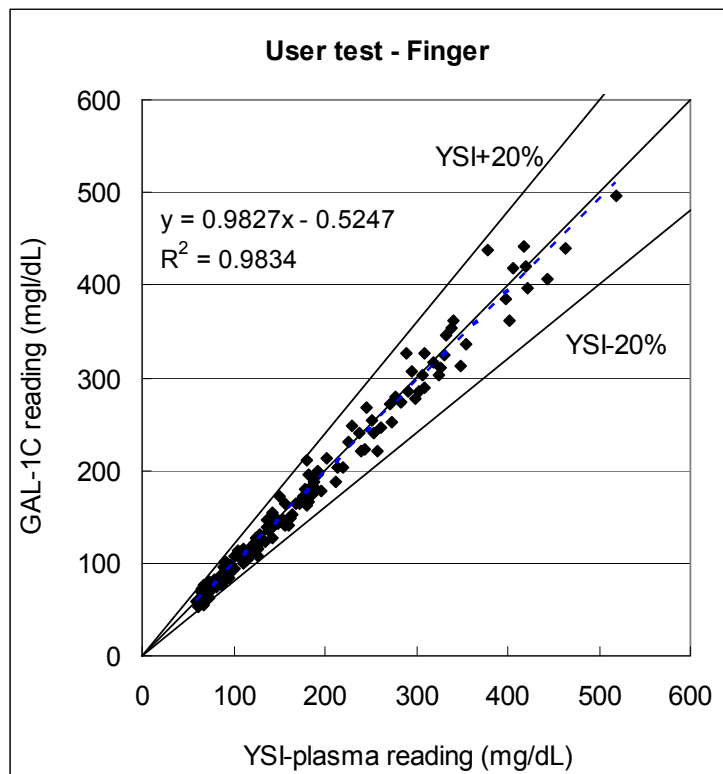
Exhibit 1: Regression Analysis of User Tests

A. Regression data

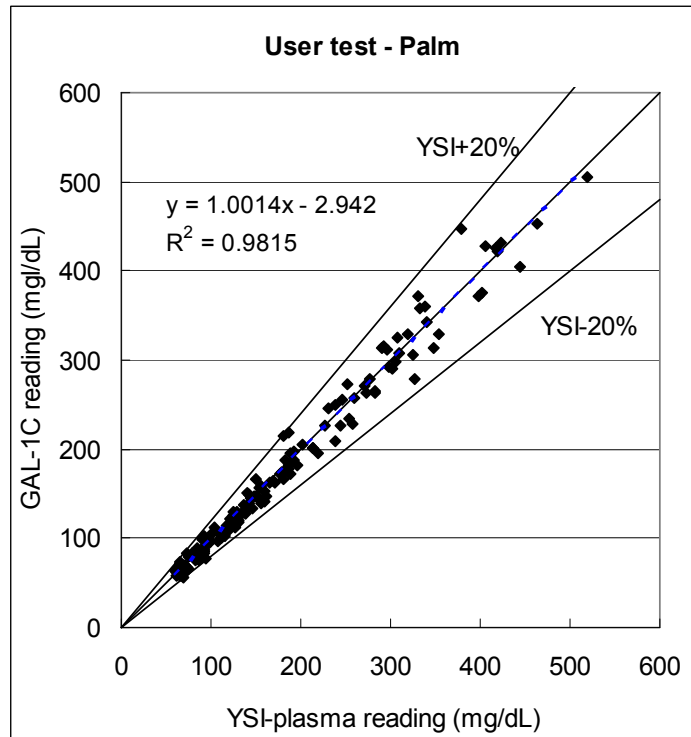
Test site	Sample numbers	Glucose concentration (mg/dL)	R ² value	Slope
Fingertip	145	60 – 519	0.983	0.983
Palm	145	60 – 519	0.982	1.001
Forearm	145	60 – 519	0.982	0.999

B. Scatter Plots

(1) User Finger Test



(2) User Palm Test



(3) User Forearm Test

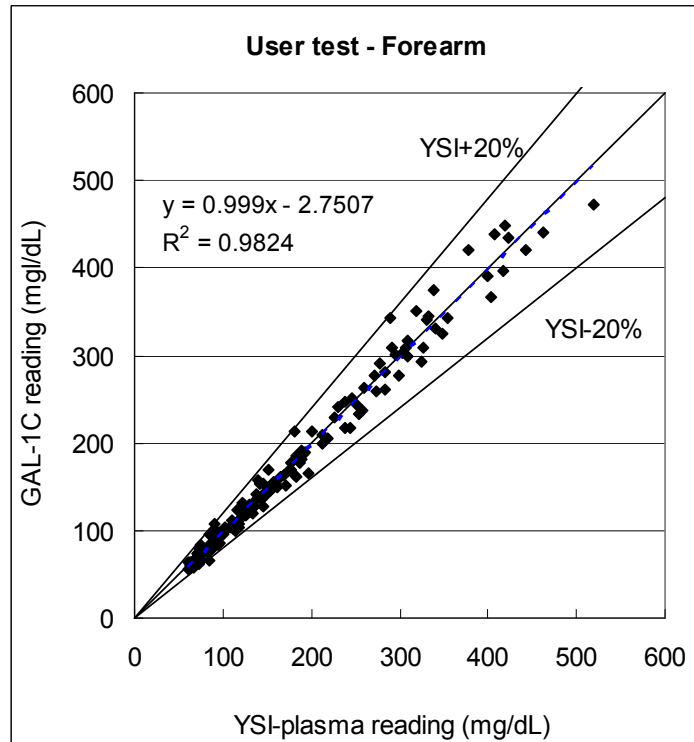


Exhibit 2: Bias Analysis of User Tests

A. Bias Distribution

(1) Finger Test:

for blood glucose <75 mg/dL:

Bias range	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
N in total (%)	10/21 (48%)	18/21 (86%)	21/21 (100%)

for blood glucose ≥ 75 mg/dL

Bias range	Within ±5%	Within ±10%	Within ±15%	Within ±20%
N in total (%)	62/124 (50%)	106/124 (86%)	122/124 (98%)	124/124 (100%)

for total samples

Total within criteria
144/145 (99%)

(2) Palm Test:

for blood glucose <75 mg/dL:

Bias range	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
N in total (%)	9/21 (43%)	19/21 (91%)	21/21 (100%)

for blood glucose ≥ 75 mg/dL

Bias range	Within ±5%	Within ±10%	Within ±15%	Within ±20%
N in total (%)	58/124 (47%)	103/124 (83%)	120/124 (97%)	124/124 (100%)

for total samples

Total within criteria
145/145 (100%)

(3) Forearm Test:

for blood glucose <75 mg/dL:

Bias range	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
N in total (%)	12/21 (57%)	19/21 (91%)	21/21 (100%)

for blood glucose ≥ 75 mg/dL

Bias range	Within ±5%	Within ±10%	Within ±15%	Within ±20%
N in total (%)	56/124 (45%)	102/124 (82%)	119/124 (96%)	123/124 (99%)

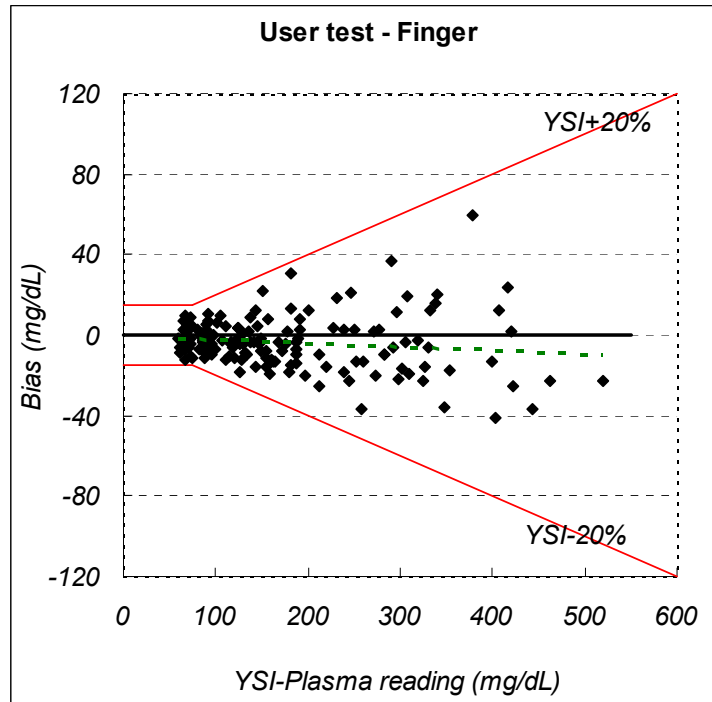
for total samples

Total within criteria
144/145 (99%)

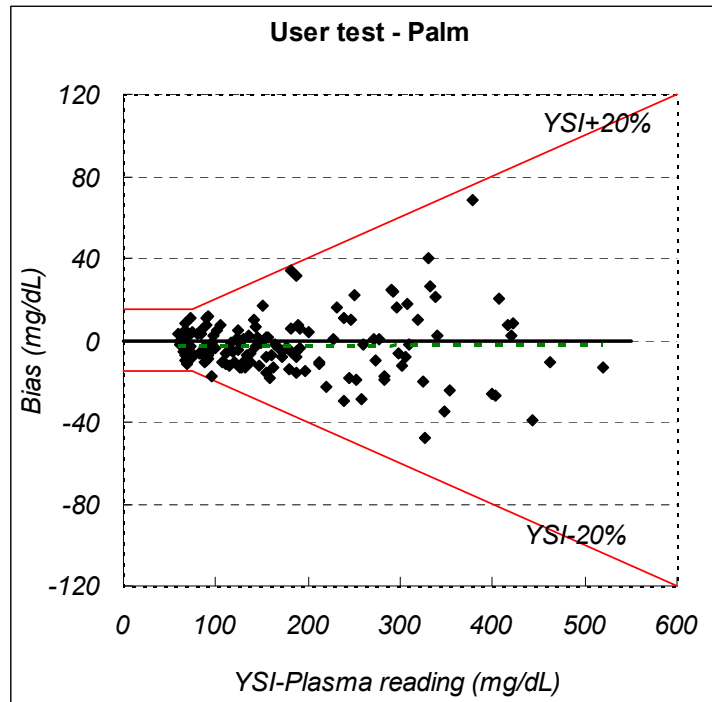
Acceptance criteria of user tests: 95% within ±20% or ±15mg/dL for glucose level ≥ 75mg/dL or < 75mg/dL, respectively

B. Bias Plot

(1) User Finger Test



(2) User Palm Test



(3) User Forearm Test

