

WOODLEY
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Veterinary Glucometer Evaluation Data

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1. Purpose

To evaluate system accuracy with animal venous whole blood (dogs), and perform the test result according to ISO 15197: 2013.

2. Material

2.1 48 Dog venous whole blood samples

2.2 9 g-Pet PLUS blood glucose meters.

2.3 3 Blood glucose test strips.

Lot 1: R20151207-1

Lot 2: R20151207-2

Lot 3: R20151207-3

2.4 Capillary tube and capillary centrifuge

2.5 YSI 2300, YSI 2747 and YSI 2356 gold standard

3. Procedure:

3.1 Ensured meters were workable and the correct code was inputted.

3.2 Confirmed the HCT of 48 samples with capillary tube and capillary centrifuge.

3.3 Confirmed blood glucose levels with YSI 2300.

3.4 Inserted the test strips into the meters and entered test mode.

3.5 Applied blood samples to the test strips.

3.6 Recorded test result and analysed the data.

4. Acceptance criteria

4.1 95% bias must be $< \pm 15\text{mg/dL}$ when blood glucose $< 100\text{mg/dL}$

4.2 95% bias must be $< \pm 15\%$ when blood glucose $\geq 100\text{mg/dL}$.

4.3 99% test result must fall in zone A and B in CEG plot.

5. Test result (please refer to appendix for raw data)

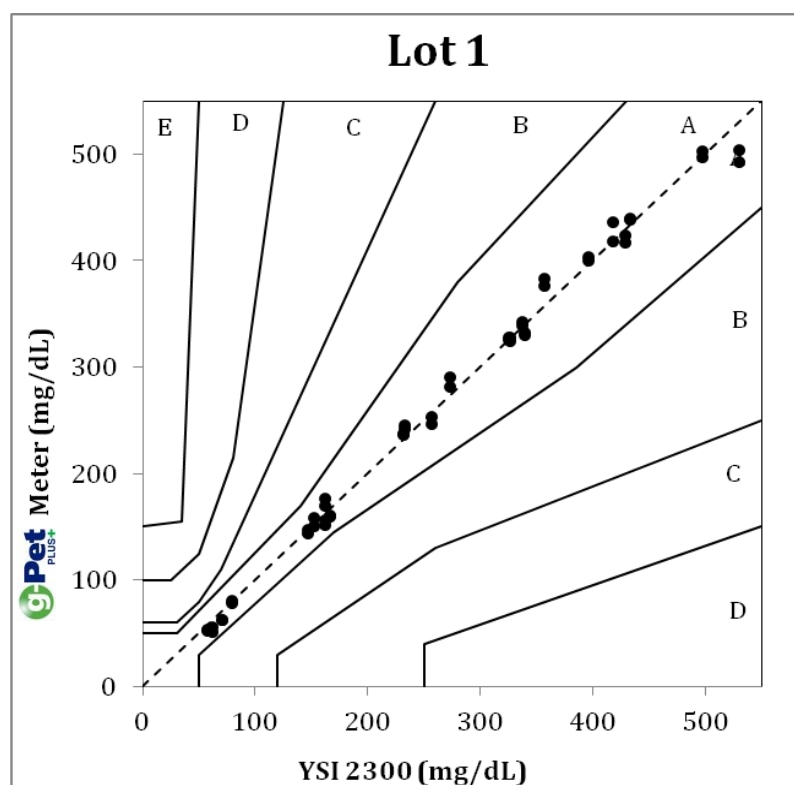
5.1 Lot 1

5.1.1 System accuracy results

System accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL)					
Within ± 0.28 mmol/L (Within ± 5 mg/dL)		Within ± 0.56 mmol/L (Within ± 10 mg/dL)		Within ± 0.83 mmol/L (Within ± 15 mg/dL)	
3/8	37.5%	7/8	87.5%	8/8	100.0%

System accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL)					
Within ± 5%		Within ± 10%		Within ± 15%	
33/40	82.5%	40/40	100.0%	40/40	100.0%

5.1.2 CEG plot



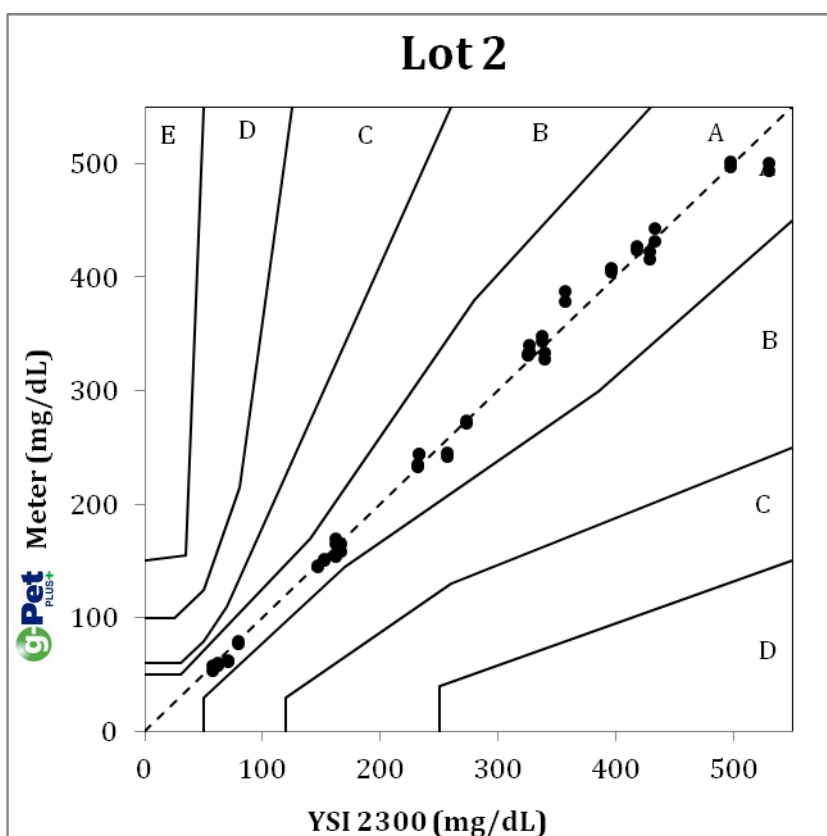
5.2 Lot 2

5.2.1 System accuracy results

System accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL)					
Within ± 0.28 mmol/L (Within ± 5 mg/dL)		Within ± 0.56 mmol/L (Within ± 10 mg/dL)		Within ± 0.83 mmol/L (Within ± 15 mg/dL)	
6/8	75.0%	8/8	100.0%	8/8	100.0%

System accuracy results for glucose concentration ≥ 5.55 mmol/L (≥ 100 mg/dL)					
Within $\pm 5\%$		Within $\pm 10\%$		Within $\pm 15\%$	
34/40	85.0%	40/40	100.0%	40/40	100.0%

5.2.2 CEG plot



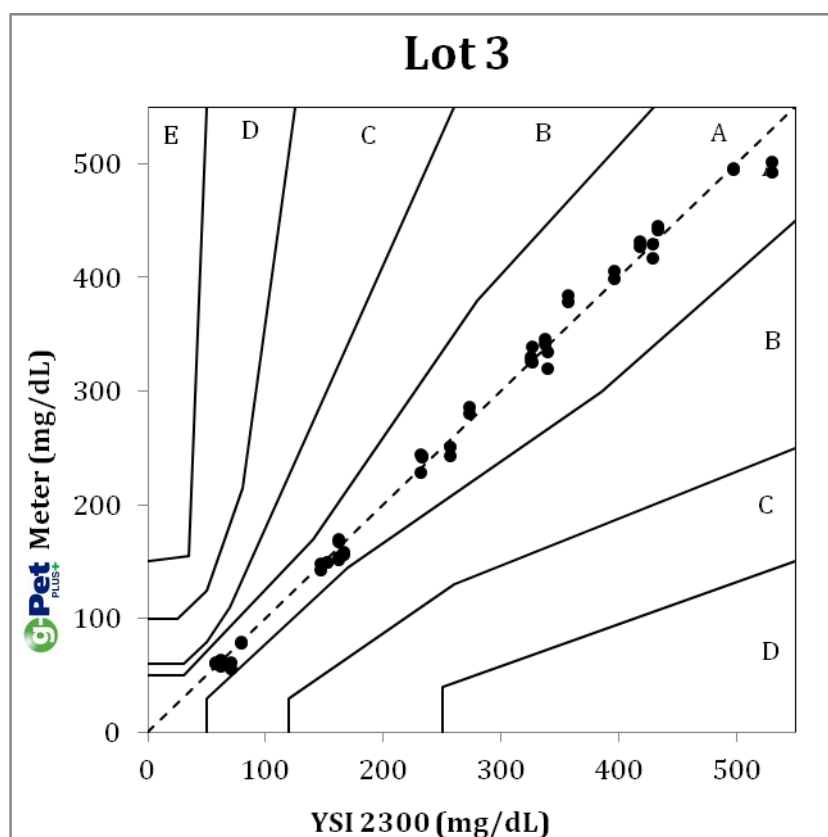
5.3 Lot 3

5.3.1 System accuracy results

System accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL)					
Within ± 0.28 mmol/L (Within ± 5 mg/dL)		Within ± 0.56 mmol/L (Within ± 10 mg/dL)		Within ± 0.83 mmol/L (Within ± 15 mg/dL)	
6/8	75.0%	7/8	87.5%	8/8	100.0%

System accuracy results for glucose concentration ≥ 5.55 mmol/L (≥ 100 mg/dL)					
Within $\pm 5\%$		Within $\pm 10\%$		Within $\pm 15\%$	
30/40	75.0%	40/40	100.0%	40/40	100.0%

5.3.2 CEG plot



6. Conclusion

No.	Acceptance criteria	Test result	Audit
1	95% bias must be $< \pm 15\text{mg/dL}$ when blood glucose $< 100\text{mg/dL}$	Lot 1: 100% Lot 2: 100% Lot 3: 100%	Pass
2	95% bias must be $< \pm 15\%$ when blood glucose $\geq 100\text{mg/dL}$.	Lot 1: 100% Lot 2: 100% Lot 3: 100%	Pass
3	99% test result must falls in zone A and B in CEG plot	Lot 1: 100% Lot 2: 100% Lot 3: 100%	Pass

All test results met the acceptance criteria, the system accuracy of g-Pet PLUS blood glucose monitoring system complies with ISO 15197: 2013.

Appendix: raw data

NO.	Ht	YSI	Lot 1	Lot 2	Lot 3
1	45	58	52	58	61
2	45	58	54	53	59
3	45	147	147	145	149
4	45	147	144	146	143
5	45	326	328	334	324
6	45	326	324	339	339
7	45	433	441	430	446
8	45	433	438	441	443
9	45	357	383	385	385
10	45	357	377	376	379
11	46	71	63	62	56
12	45	61.5	52	60	58
13	45	61.5	57	58	64
14	45	152	158	152	149
15	45	152	150	150	150
16	45	232	238	234	245
17	45	232	236	232	228
18	45	325	328	330	328
19	45	325	326	329	330
20	45	396	404	407	400
21	45	396	401	404	406
22	45	497	497	499	496
23	45	497	503	495	496
24	46	71	62	62	60
25	46	167	160	158	158
26	46	167	161	164	156
27	46	257	254	241	243
28	46	257	246	244	252

29	46	340	333	326	335
30	46	340	330	331	322
31	46	429	425	414	417
32	46	429	418	420	429
33	46	530	504	498	492
34	46	530	492	492	502
35	45	233	245	243	242
36	45	233	243	243	243
37	46	162	156	155	154
38	46	162	152	153	153
39	46	79	82	79	78
40	46	79	78	77	79
41	46	162	177	170	171
42	46	162	170	164	169
43	46	273	291	273	287
44	46	273	282	269	281
45	46	337	342	346	342
46	46	337	339	343	347
47	46	418	419	426	428
48	46	418	436	422	432