Clinical Evaluation of the Hand-Held Abbott AlphaTRAK™ Blood Glucose Monitoring System for Use With Dog and Cat Blood Samples

Elizabeth M. Cozzi, Ph.D.; Claire N. Harris; Andrew J. Lawrence; Roy Semon; Shridhara Alva, Ph.D. and Matthew M. Widman
Abbott, Abbott Park, IL

Background

Diabetes mellitus is a common disorder of dogs and cats. Monitoring of patient blood glucose levels is an essential element of diabetes management; however, hand-held instruments designed for convenient glucose monitoring in humans are not validated for veterinary use.

Abbott AlphaTRAK™ is a hand-held glucose monitoring device specifically developed for veterinary use. This work represents the first study of the performance of the device in the clinical setting.

Purpose

To compare the accuracy of Abbott AlphaTRAK™ and two other hand-held devices against the reference method used by Antech Laboratories, for measurement of blood glucose in diabetic and non-diabetic dogs and cats.

Methods and Design

- Diabetic and non-diabetic dogs and cats were recruited at six veterinary clinics. In some cases, more than one sample was taken from diabetic animals at various times following insulin treatment.
- Venous whole blood samples were taken and tested immediately on each of three hand-held glucose monitoring devices: Abbott AlphaTRAK™, Bayer Ascensia® Contour™ and Roche Accu-Chek® Advantage.
- Plasma samples were then prepared according to standard practices at the clinic and submitted to Antech Laboratories for glucose testing. Antech testing is considered the "Gold Standard" for veterinary blood glucose measurement.
- All instrument calibration and testing was performed in accordance with the manufacturer's instructions.
- Accuracy was determined for each instrument by calculating % Antech Reference as follows:

  Hand-Held Meter Glucose Levels/Antech Reference Glucose Levels

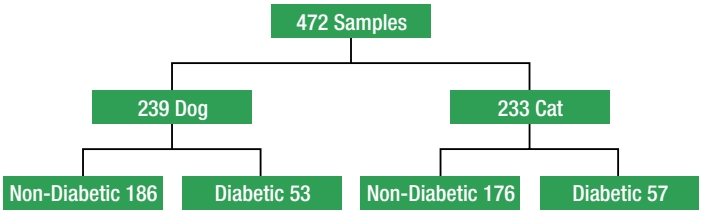
  Bias of results compared to Antech was calculated as follows:

Bias = Hand-Held Meter Response – Antech Reference
%Bias = 100 * (Hand-Held Meter Response – Antech Reference)/ Antech Reference

The biases of the three hand-held devices were compared to zero at the 5% significance level.

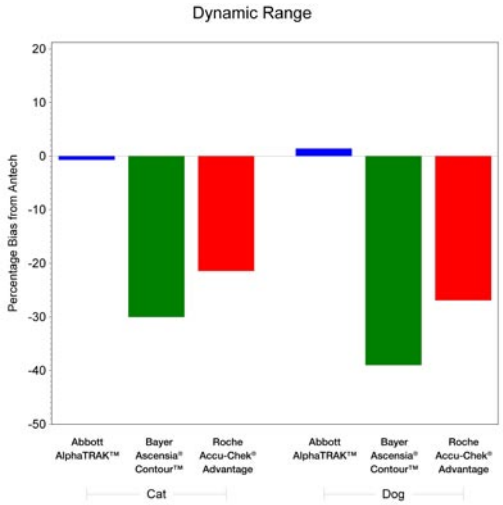
Results

A total of 472 samples were taken from 452 animals. Sample distribution is shown below.

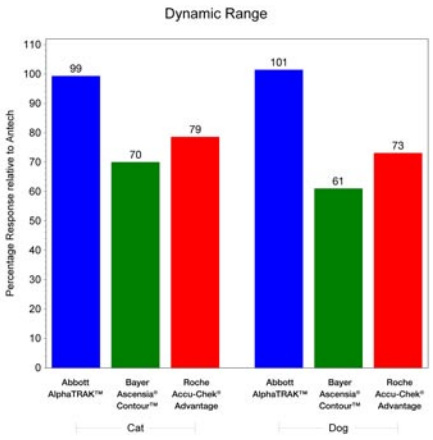


Accuracy

Summary of Bias Results Relative to Antech



Summary of Accuracy Results



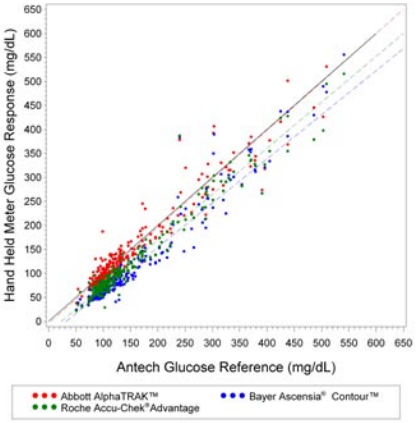
Abbott Animal Health

Hand-Held Meter	Glucose Reference (mg/dL)	Animal (n)	Mean Bias (mg/dL)	Mean % Bias	% Relative to Antech
Abbott AlphaTRAK™	Antech	Cat (232)	-1.97	-0.71	99.29
		Dog (236)	-2.68	1.42	101.42
Bayer Ascensia® Contour™	Antech	Cat (233)	-38.44	-30.02	69.98
		Dog (237)	-49.01	-38.99	61.01
Roche Accu-Chek® Advantage	Antech	Cat (233)	-28.54	-21.42	78.58
		Dog (239)	-34.71	-26.89	73.11

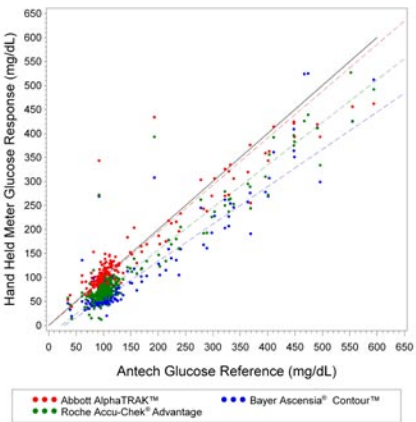
For the Abbott AlphaTRAK™ hand-held meter, the mean % bias, for both cat and dog blood samples are not significantly different from zero at the 5% significance level (p=0.47 and p=0.40, respectively). This provides strong evidence that Abbott AlphaTRAK™ results are statistically equivalent to the Antech results.

For the Bayer Ascensia® Contour™ and Roche Accu-Chek® Advantage hand-held meters, the mean % biases for both cat and dog blood samples are significantly different from zero at the 5% significance level (p<0.0001 for all cases). This is strong evidence that Bayer Ascensia® Contour™ and Roche Accu-Chek® Advantage results are statistically different from the Antech reference results.

Comparison of Hand-Held Monitor Results to Those of Antech – Cat Blood



Comparison of Hand-Held Monitor Results to Those of Antech – Dog Blood



Regression

Regression analysis was performed and intercepts, slopes and correlation coefficients were calculated for each hand-held instrument versus the Antech reference results.

Summary of Regression Statistics

Hand-Held Meter	Animal	Intercept (mg/dL)	Slope	r	n
Abbott AlphaTRAK™	Cat	-4.5	1.01	0.96	232
	Dog	-0.3	0.98	0.94	236
Bayer Ascensia® Contour™	Cat	-29.6	0.92	0.97	233
	Dog	-22.5	0.78	0.94	237
Roche Accu-Chek® Advantage	Cat	-22.5	0.97	0.98	233
	Dog	-20.4	0.89	0.95	239

For the Abbott AlphaTRAK™ hand-held meter, the intercept and slope for cat blood samples are not significantly different from the line of equivalency (intercept: 0, slope: 1), at the 5% significance level, (p=0.17 and p=0.58, respectively). There is also no significant difference for the dog blood samples, (p=0.93 and p=0.33, respectively). This provides strong evidence that Abbott AlphaTRAK™ results are statistically equivalent to the Antech results, at all glucose values.

For both the Bayer Ascensia® Contour™ and Roche Accu-Chek® Advantage meters, the slopes and intercepts are statistically different from the line of equivalency (p<0.01 in all cases). This is evidence that both the Bayer and Roche meter results are not statistically equivalent to the Antech results.

Conclusions

The accuracy of Abbott AlphaTRAK™ was shown to be superior to that of Bayer Ascensia® Contour™ and Roche Accu-Chek® Advantage. On average, Abbott AlphaTRAK™ results were within 2% of Antech results in a population of diabetic and non-diabetic dogs compared to a range of 27 – 39% for comparator instruments. In a population of diabetic and non-diabetic cats, Abbott AlphaTRAK™ results were on average within 1% of Antech results, compared to a range of 21 – 30% for comparator instruments.

