Clinical Evaluation of the Abbott AlphaTRAK 2 Portable Blood Glucose Meter (PBGM) for Testing of Canine and Feline Blood Samples
Elizabeth M. Cozzi, Ph.D., Robert Cedergren, Ph.D., Abbott Laboratories, Abbott Park, IL U.S.A.

Background

Diabetes mellitus is a common canine and feline disorder. Blood glucose monitoring is an essential element of diabetes management. Portable Blood Glucose Meters (PBGMs) designed for blood glucose monitoring in humans are not validated for veterinary use. Abbott Animal Health has developed the AlphaTRAK Blood Glucose Monitoring System that is specifically calibrated and validated for different species to be used in the veterinary market.

The AlphaTRAK 2 meter and test strip are the next generation AlphaTRAK Blood Glucose Monitoring System. The AlphaTRAK 2 meter is compatible with AlphaTRAKer Electronic Data Master designed to help track, manage and analyse information about diabetic pets electronically. The AlphaTRAK 2 test strip automatically turns the meter on and its improved sample area makes testing fast and easy. The AlphaTRAK 2 system uses variable species-specific codes to get accurate test results for different species and to decrease lot-to-lot variability.

Purpose

To compare the accuracy of the AlphaTRAK 2 meter and two other PBGMs against the reference method used by Antech Laboratories for measurement of blood glucose in diabetic and non-diabetic canines and felines.

Methods and Design

• Diabetic and non-diabetic canines and felines were recruited at two veterinary practices. In some cases, more than one sample was taken from diabetic animals at various times following the insulin treatment.

• Whole blood samples were taken and tested immediately on each of the PBGMs: AlphaTRAK 2, Contour®† and Accu-Chek® Aviva. Each sample was tested with three different AlphaTRAK 2 test strip lots.

• Plasma samples were prepared according to standard practices at the practice and submitted to Antech 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.

Data Analysis

Accuracy was determined for each instrument by calculating the following:

% Antech Reference = PBGM Response/Antech Reference

Bias of results compared to Antech was calculated as following:

Bias = PBGM Response – Antech Reference

% Bias = 100* (PBGM Response – Antech Reference)/Antech Reference

The biases of the three PBGMs were compared to zero using paired t-tests (SigmaStat 2.0) at the 5% significance level (SigmaStat 2.0).

Results

Summary of Bias Results Relative to Antech

The summary of the results is shown below:

Summary of Accuracy Results Relative to Antech

A total of 104 samples were taken from 78 animals. Sample distribution is shown below.
The AlphaTRAK 2 PBGM mean % biases in measuring canine and feline blood glucose were significantly lower than those of the other two PBGMs at the 5% significance level. The AlphaTRAK 2 PBGM results for canine blood glucose were statistically equivalent to those of the Antech reference while the comparator PBGM results were statistically different from those of the Antech reference.

**Conclusions**

Based on this study, the accuracy of the AlphaTRAK 2 meter in measuring blood glucose in canine and feline blood is superior to that of the Contour and Accu-Chek Aviva PBGMs. In a population of diabetic and non-diabetic canines, the AlphaTRAK 2 meter results were on average within 1% of Antech reference results compared to a range of 23-29% for comparator PBGMs. In a population of diabetic and non-diabetic felines, the AlphaTRAK 2 meter results were on average within 2% of Antech reference results compared to a range of 19-24% for comparator PBGMs.