

## Clinical Comparison of Two Veterinary Portable Blood Glucose Monitors for Testing Dog and Cat Samples

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### Summary

In a clinical study of 50 dogs and 50 cats, the Henry Schein Vet GlucoGauge (VGG) and the Zoetis AlphaTrak2 (AT2) portable blood glucose monitoring (PBGM's) systems were compared versus the reference glucose method<sup>1</sup> on capillary and venous samples. The VGG demonstrated higher accuracy with low bias versus the reference glucose method results in both dogs and cats. The AT2 demonstrated lower accuracy and had a higher bias relative to the reference glucose method results in both dogs and cats.

### Background

Diabetes Mellitus (DM) is a common disease in dogs and cats. Actual diabetes incidence estimates vary significantly, but experts agree it is both under diagnosed and the incident is increasing rapidly. Banfield Pet Hospital's State of Pet Health 2016 Report<sup>2</sup> states:

*"In 2011, we reported a 32 percent increase in canine diabetes and a 16 percent increase in feline diabetes since 2006. Unfortunately, diabetes continues to grow in prevalence among dogs. Canine diabetes has increased by 79.7 percent since 2006, while, in felines, the prevalence of diabetes has increased 18.1 percent over the same time frame."*

In a landmark position paper published by the American Association of Animal Hospitals,<sup>3</sup> AAHA recommended the following:

*"The mainstay of treatment for clinical DM in both species is insulin, along with diet modification."*

*"Home monitoring of blood glues (BG) is ideal and strongly encouraged..."*

*"Home BG monitors should be ... calibrated for dogs and cats."*

These and other recommendations have resulted in a shift and need for pet owners to have the ability to conduct home BG testing. Home BG testing provides reliable information to the veterinarian in order to help attain and maintain a more effective insulin and diet regimen which will lead to better outcomes.

### Purpose:

Compare the performance of two Portable Blood Glucose Monitors (PBGM) specifically calibrated for dogs and cats versus reference method. Data will be analyzed for accuracy and bias relative to reference method for both capillary and venous samples. Accuracy and bias comparisons between both PBGM's and reference results were compiled and are presented herein. Accuracy of both meters is also compared to U.S. FDA accuracy standards for glucose meters.

### Protocol and the Comparison Sheet

The U.S. Food and Drug Administration (FDA) has established standards for all human glucose meters marketed in the United States. They follow the International Organization for Standardization (ISO) 15197:2003.<sup>4</sup> Glucose meters specifically calibrated and used for animals are also under the purview of the FDA, but specific standards have been established since the meters are only indicated for animal use. Nonetheless all animal glucose meter manufacturers voluntarily ascribe to the human meter standards in developing their systems.



The applicable FDA glucose meter accuracy standards for these two meters are broken into two parts based on two separate and absolute ranges of the glucose results, as follows:

1. FOR GLUCOSE REFERENCE RESULTS LESS THAN 75 mg/dL (hypoglycemic range) :  
**At least 95% of the meter results must be within +/- 15 mg/dL of the reference result**
2. FOR GLUCOSE REFERENCE RESULTS 75 mg/dL OR HIGHER (normal and hypoglycemic ranges) :  
**At least 95% of the meter results must be within +/- 20% of the reference result**

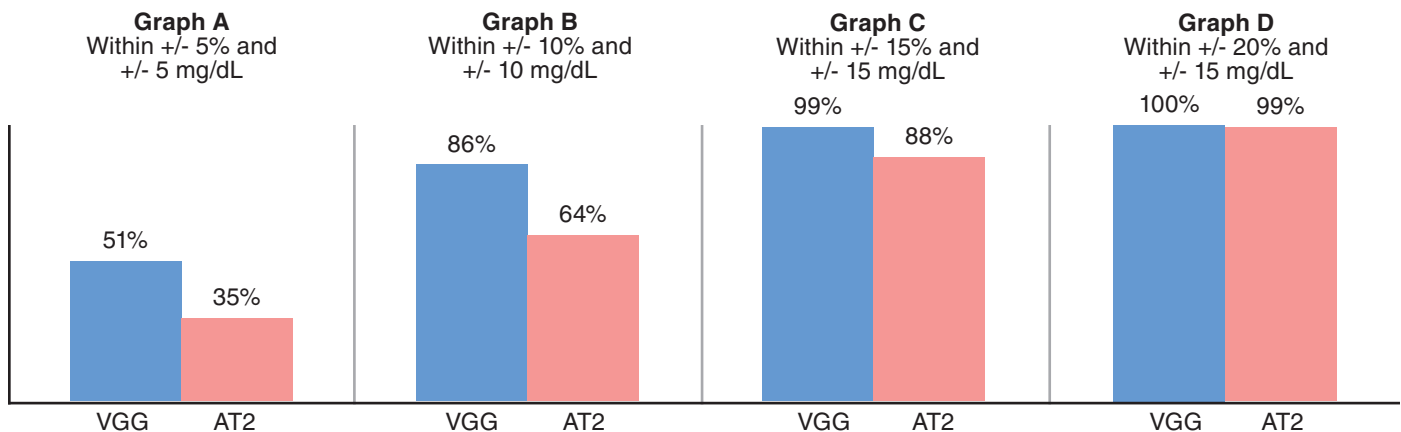
Thus, for Range 1, if the reference result is 70 mg/dL: *Meter results should be from 55–85 mg/dL (95% of the time).*  
For Range 2, if the reference result is 400 mg/dL: **Meter results should be from 320–480 mg/dL (95% of the time)**

**Important Note:** The FDA states that a PBGM’s intended use is for the quantitative measurement of glucose in whole blood or venous samples by healthcare professionals in clinical settings or in whole blood by lay users at home to assist in the ongoing evaluation and management of patients with diabetes. They are to be used for monitoring; not for diagnosis or screening. **No diagnosis should be made nor should any treatment be changed based on a single PBGM result.**

### Performance – Overall Accuracy of VGG and AT2 versus Reference Results

The following data shows the cumulative percentage of 200 results for each meter versus reference results over four accuracy intervals within the overall FDA accuracy range guidelines:

- **Graph A:** All results within 5% (when 75 mg/dL and higher) and within 5 mg/dL (when under 75 mg/dL)
- **Graph B:** Same as above, but includes results within 10% and 10 mg/dL, respectively
- **Graph C:** Same as above, but includes results within 15% and 15 mg/dL, respectively
- **Graph D:** Same as above, but includes results within 20% and 15 mg/dL, respectively



### Discussion:

Graphs A through D show the cumulative total percent of results for the four range increments. Graph A, for example, shows that over half of VGG results (51%) were within the 5%/5 mg/dL increment while only 35% of the AT2 results fell in the same range. Graph B shows VGG at 86% of the results falling within the 10%/10mg/dL increment, while AT2 had 64% that fell in that rang. For the VGG there were no results that fell outside of the FDA’s “outlier” limits (“at least 95% of results...”) while 1% of the AT2 results (2 of the 200 total results) were considered “outliers”.

This series of graphs demonstrates that Vet GlucoGauge results appear to be closer to reference results more often than the AT2 results.

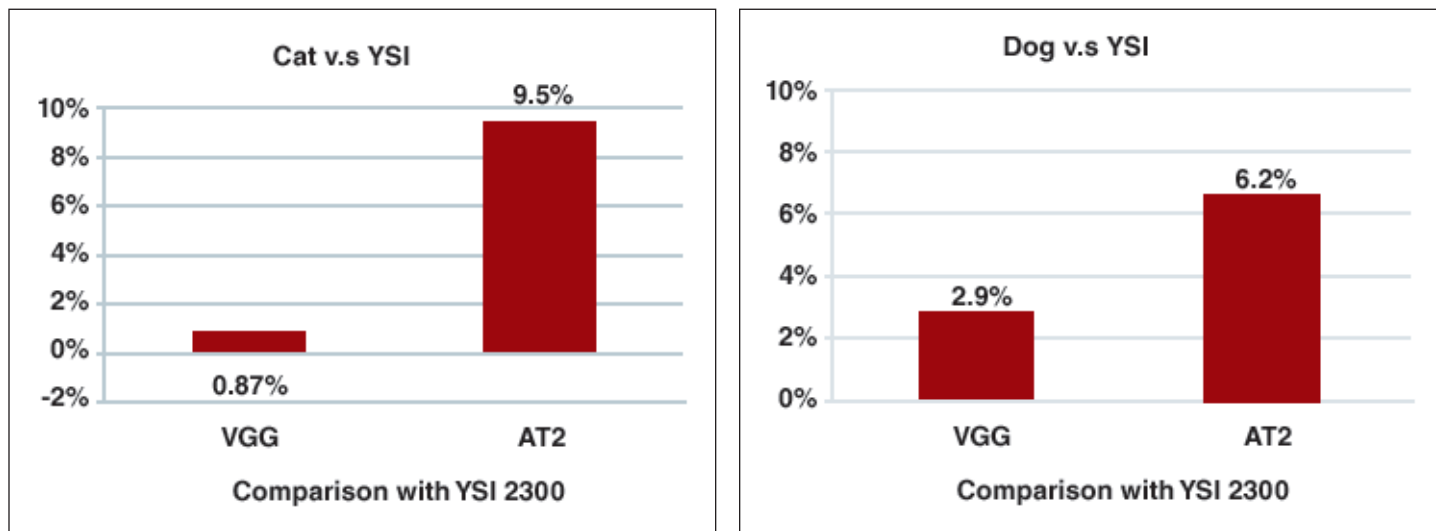


## Performance—Overall Bias of VGG and AT2 versus Reference Results

The overall comparison data for the two meters were also analyzed for bias with respect to reference results. Simply speaking, bias is present if a system tends to consistently provide higher (or lower) results versus reference values.

The charts below represent **Overall Average Percent Bias** versus reference results for the VGG and AT2 for dogs and cats for all samples.

Figure 1



For cats, the VGG showed low overall bias (+0.8%) versus reference, whereas the AT2 showed positive bias (+9.5%). For dogs, both systems showed a positive bias but VGG bias was a relatively small (+2.9%) where as the AT2 again showed higher positive bias of 6.2%.

### Conclusion:

**The Henry Schein Vet GlucoGauge Blood Glucose Monitoring System is an accurate tool for glucose monitoring of diabetic dogs and cats in veterinary clinics, animal hospitals and for testing at home under the supervision of the veterinarian.**

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<sup>1</sup> Reference glucose method is the Yellow Springs International STAT Plus Glucose Analyzer. The YSI 2300 STAT Plus Glucose Analyzer (YSI 2300) which is widely accepted as a method for reference measurements and system calibration by most manufacturers of blood glucose (BG) monitoring systems worldwide.

<sup>2</sup> Banfield Pet Hospital State of Pet Health 2016 Report. Available at: [www.banfield.com/state-of-pet-health](http://www.banfield.com/state-of-pet-health)

<sup>3</sup> 2010 AAHA Diabetes Management Guidelines for Dogs and Cats. Available at: [https://www.aaha.org/professional/resources/diabetes\\_management.aspx](https://www.aaha.org/professional/resources/diabetes_management.aspx)

<sup>4</sup> International Organization for Standardization. In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2003

