

Evaluation of the Henry Schein Vet GlucoGauge Portable Blood Glucose Monitoring System for Testing Dogs and Cats

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Summary

In a clinical study of 50 dogs and 50 cats, the Henry Schein Vet GlucoGauge Blood Glucose Monitoring System was shown to be an excellent 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. The system provides excellent correlation versus reference results over a wide range of blood glucose levels in both dogs and cats with either capillary and venous samples.

The Henry Schein Vet GlucoGauge System

The Henry Schein Vet GlucoGauge (VGG) System is specifically calibrated for dogs and cats to provide accurate results in veterinary clinics, animal hospitals, research laboratories and in home glucose monitoring. The system uses the smallest sample for testing (0.3 microliters) and can be used on capillary or venous samples. The VGG does not require the use of specific codes or code chips that must be entered or changed in the meter based on the lot number of the test strips and the species being tested. As such, the VGG system is easier to use and can eliminate potential errors associated with the failure to check and/or change the meter to the proper code or code chip for the test strip lot number and the species being tested. The meter also provides the ability to review past results and positively determine that results were performed in the proper mode for the species being tested, a feature unavailable on other animal glucose meters. A downloadable Data Management System is also available.

Background

Diabetes Mellitus (DM) is a common disease in dogs and cats. Actual diabetes incidence estimates vary tremendously, but experts agree it is both under diagnosed and increasing rapidly. A Banfield Pet Hospital's State of Pet Health 2012 Report¹ states that diabetes is increasing faster than any of the top 5 medical conditions in dogs and cats.

In a landmark position paper published by the American Association of Animal Hospitals², AAHA recommend the following:

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

"Home glucose monitoring is ideal and strongly encouraged..."

"Home blood glucose monitors should be (specifically) calibrated for dogs and cats."

These and other recommendations have resulted in a tremendous shift to home testing in recent years. Home testing provides better information to the veterinarian to help attain and maintain a more effective insulin and diet regimen which ultimately leads to better outcomes.

Purpose

To assess the accuracy of the results from the Vet GlucoGauge system compared to reference method. Data will be analyzed for accuracy and bias relative to reference method and compared to FDA and ISO standards^{3,4} for Portable Blood Glucose Meters (PBGM's).

Protocol

A total of 50 dogs and 50 cats were used in the study. Two capillary samples from each animal were collected for analysis on two Vet GlucoGauge meters. Simultaneously one venous whole blood sample was obtained from each animal for analysis by the Vet GlucoGauge meters. Venous samples were then centrifuged and the resulting plasma was tested on the YSI 2300 Stat Plus glucose analyzer as the reference result (see "Reference Method", below). All system preparation, calibration and testing was performed in accordance with the manufacturer's instructions.

Data Analysis

Accuracy was determined by calculating the following:

$$\% \text{ Reference} = (\text{Vet GlucoGauge Result} / \text{Reference Result}) \times 100\%$$

Bias of results compared to reference was calculated as follows:

$$\text{Actual Bias} = \text{Vet GlucoGauge Result} - \text{Reference Result}$$

$$\% \text{ Bias} = (\text{Vet GlucoGauge Result} - \text{Reference Result}) / \text{Reference Result} \text{ (expressed as a percentage)}$$

Results will also be assessed to determine if they meet FDA and ISO standards for accuracy for all human PBGM's. Glucose meters specifically calibrated for animals are technically not governed by the FDA/ISO standards since the meters are not indicated for human use, but all animal glucose meter manufacturers do voluntarily utilize these standards in developing their systems.

FDA glucose meter accuracy standards mirror the ISO standards and are broken into two parts based on two separate and important absolute ranges of the glucose results, as follows:

1) FOR GLUCOSE RESULTS LESS THAN 75 mg/dL (reference method):

95% of the meter results must be within +/- 15 mg/dL of the reference result

2) FOR GLUCOSE RESULTS 75 mg/dL OR HIGHER (reference method):

95% of the meter results must be within +/- 20% of the reference result

Example 1: If the reference result is 70 mg/dL:

Meter results must be from 55 – 85 mg/dL (95% of the time)

Example 2: If the reference result is 400 mg/dL:

Meter results must be from 320 - 480 mg/dL (95% of the time)

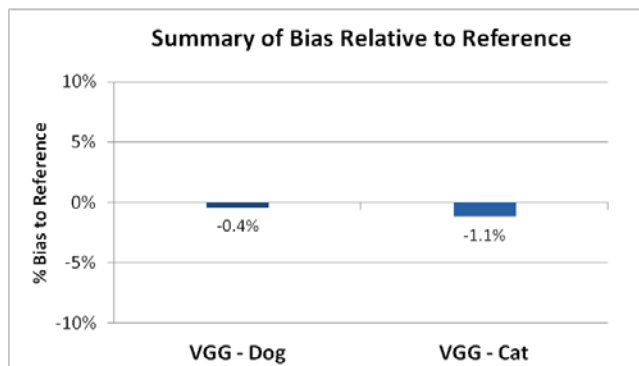
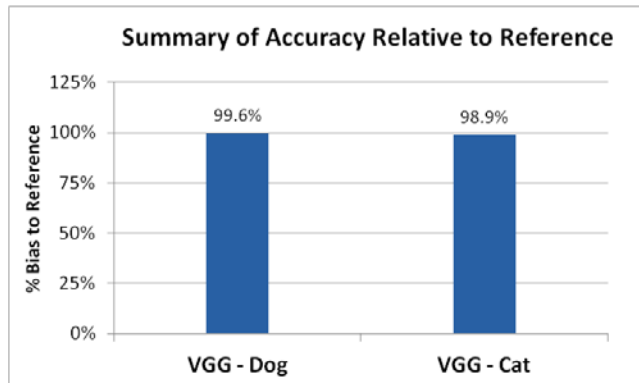
Note: The FDA states that PBGM's intended use is for the quantitative measurement of glucose in whole blood or venous samples by healthcare professionals in clinical settings or in whole blood by lay users at home to assist in the ongoing evaluation and management of patients with diabetes. They are 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.

Results – Overall Accuracy & Bias

The charts below show that overall VGG results achieved 99.6% and 98.9% accuracy for dogs and cats, respectively, relative to reference results (top chart). Conversely, overall VGG result bias was on average a minimal 0.4% and 1.1% below the reference results for dogs and cats, respectively (bottom chart).

This indicates that the Vet GlucoGauge system demonstrates excellent overall accuracy with minimal bias for results on both species with venous and capillary samples relative to reference results.



Results analysis also indicated the Vet GlucoGauge system exceeded FDA and ISO accuracy standards relative to reference for both species when using venous and capillary samples⁵, as follows:

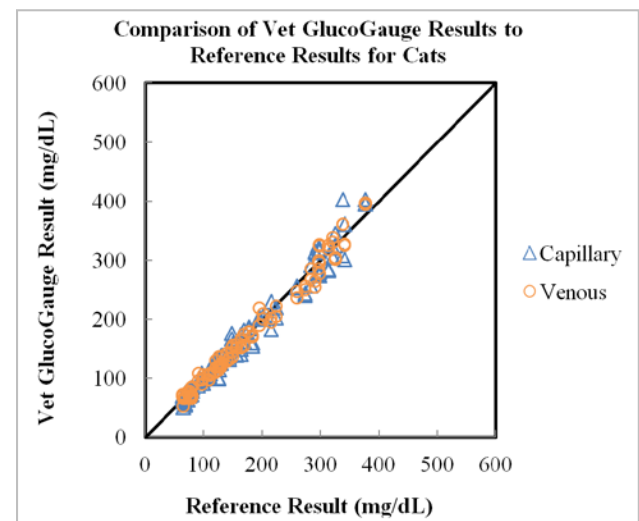
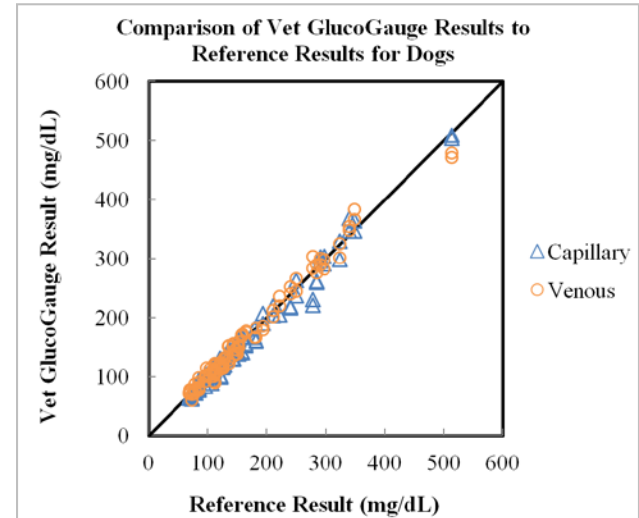
100% of the VGG study results fell within the +/- 15 mg/dL range for results less than 75 mg/dL; and

100% of the Vet GlucoGauge study results fell within the +/- 20% mg/dl range for results 75 mg/d and higher.

Results – Correlation & Linearity

The correlation charts below plots the values of the VGG results (Y axis) versus the respective reference results (X axis) for all venous and capillary results.

(Note: If all results were equal, all points would fall exactly on the 45 degree line -the line of equality. This would indicate perfect correlation and linearity with no bias.)



The above comparison charts show the Vet GlucoGauge system demonstrates excellent correlation and linearity for both dogs and cats. This is indicated by the tight scatter of the comparison points along the equality line over the full range of sample results on both venous and capillary results.

In summary, the Henry Schein Vet GlucoGauge Blood Glucose Monitoring System was shown to be an excellent 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.

References:

1. Banfield State of Pet Health 2012 Report, Banfield Pet Hospital, Vancouver, WA.
2. "AAHA Diabetes Management Guidelines for Dogs and Cats". Journal of the American Animal Hospital Association 2010; 46:215-224.
3. U.S. Food and Drug Administration Guidelines for Portable Blood Glucose Meters, US FDA Food and Cosmetic Act
4. International Organization for Standardization (ISO)15197 (2003).
5. Data on file, Henry Schein Animal Health, Dublin, OH, USA.

Reference Method: Reference method utilized was the Yellow Springs International 2300 Stat Plus glucose analyzer. The YSI 2300 system is widely used in the U.S. and internationally as a reference method when assessing glucose and chemistry systems ranging from both human and animal glucose meters to small-to-mid-sized chemistry analyzers for use in clinics, doctors offices and hospital laboratories.