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Vet GlucoGauge Blood Glucose Monitoring System

Introducing a New Glucose Meter into the Veterinary Laboratory

Purpose

This is a protocol to introduce your new Vet GlucoGauge Blood Glucose Monitoring System (VGG) into your practice. Like most clinics, your lab may have more than one methodology that is used for obtaining glucose results. These may include a bench top chemistry analyzer, a portable blood glucose meter (PBGM) or simply sending samples to a reference lab. The clinical symptoms presented, the need for a panel versus a single result, how quickly results are needed, the cost of the result and other factors determine which method you use. When introducing any new system, it is imperative to ***assess the new system against the most accurate method available, i.e., your "reference" method***. This assessment will ultimately provide the best overall picture—and the highest degree of confidence—of how your new glucose meter will perform in your practice.

Accuracy Comparisons & Precautions

Results between various PBGM methods can vary as much as 40%. It is strongly recommended to compare each PBGM method to your best available method.

General Recommendations

Make sure operators are completely familiar with all aspects of operation of all systems involved, from routine operation, to system limitations and minor troubleshooting.

Perform quality control tests on each system according to manufacturers recommendations, and record all control results in your laboratories' control log manual.

Refer to the manufacturer's documentation for any questions, troubleshooting, etc. For questions on the VGG system, call the toll free support line at 800-836-3837.

Protocol and the Comparison Sheet

Perform at least 20 comparisons between the VGG and the reference system. These comparisons will help you gain a better understanding of the performance of the new meter. In a true clinical laboratory comparison, samples are run in duplicate on both systems.

Always use the same sample for comparison:

- For capillary whole blood samples, use the same drop of blood for the VGG and reference system.
- For venous samples, run the VGG directly from the sample and immediately run the reference system with the same sample.

Record all pertinent information on the comparison sheet, including serial numbers of meters and reference analyzer, lot numbers of test strips, reagents, control solutions, etc.

Record any sample abnormalities (such as "severe hemolysis", etc.), or unusual patient symptoms or behaviors (such as "dehydrated state") that may affect results and eliminate them from the comparison.

Do not squeeze the sample site excessively when obtaining capillary samples.

Define the specific parameters of your overall study ahead of time. Example:

> *"Comparison will be comprised of twenty (20) sets of results; 10 canine, 10 feline; 3 "normal" blood glucose results for each species and 7 hyperglycemic results for each species; all capillary samples. Reference analyzer will be (name of your reference method). Duplicate analyses will be run on each sample on both systems."*

Vet GlucoGauge Blood Glucose Monitoring System

Fill out the comparison sheet with all pertinent information regarding the clinic, operators, reference system, glucose meter information, expiration dates, solutions for reagents, test strips, and controls, etc.

For each comparison, enter the patient's name, species (c=canine, f=feline), gender (m=male, f=female), "other" information as needed, such as sample type (cap = capillary, ven = venous) and operators initials.

The results section of the comparison sheet is set up to record duplicate results from the reference system and the VGG. Alternately, it could be used to record:

- Single reference system results and single VGG results
- Single reference system results and duplicate VGG results
- Single reference system results and two different meter results (i.e., VGG and current meter)

Use a second sheet for more that 20 sets of results.

Performance Comparison Using the Results Analysis Sheet

Follow the instructions on the results analysis sheet to interpret your results in the context of the appropriate U.S. FDA accuracy guidelines for PBGM's,[1] as follows:

1. For reference system glucose results that are greater than 75 mg/dL
   At least 95% of the meter results must be within +/- 15% of the reference result.
2. For reference system glucose results that are 75 mg/dL and higher
   At least 95% of the meter results must be within +/- 20% of the reference result.

Unfortunately, the statistics tend to be valid only with very large sets of data, such as when new glucose meters are reviewed for market clearance by the FDA. The FDA applies these standards against the large sets of data submitted by the manufacturer and, if the data passes, the new meter is deemed "substantially equivalent" to other meters on the market and can therefore be sold in the U.S. We can use this concept of "substantial equivalency" in assessing your results. The table below shows the average accuracy relative to reference results for over 1,600 samples, from five currently marketed glucose meters, based on the data submitted to the FDA as presented in the test strip package inserts.[2]

Average Accuracy of Five Glucose Meters

	Within +/- 5% of Reference	Within +/- 10% of Reference	Within +/- 15% of Reference	Within +/- 20% of Reference
Number/Total	756/1645	1260/1645	1511/1645	1597/1645
Percent	**46%**	**77%**	**92%**	**97%**

This level of accuracy is representative of glucose meters on the market today—whether human or animal calibrated. If you run enough comparisons, your results will show a similar pattern. It is this "substantial equivalence" between the various makes and models of PBGM's that allows for effective diabetes management in millions of diabetic humans and diabetic pets.

Notes & References:

1. U.S. Food and Drug Administration Guidelines for Portable Blood Glucose Meters, US FDA Food and Cosmetic Act
2. Data on file, Henry Schein Animal Health, Dublin, OH, USA.

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Comparison Data Collection Sheet

Clinic: _____

In Charge: _____

Operators & Initials:

_____/_____

_____/_____

_____/_____

Reference System Manuf./ Model _____

Ref. Glucose Reagent Lot # _____

Vet GlucoGauge S/N: _____

VGG Test Strip Lot #/ Exp Date_____

VGG Date Vial Opened _____

VGG Control Lot #/Exp Date _____

VGG Control Bottle Opened: _____

#	Patient, Species, Sample & Operator Information									Ref. #1 Result mg/dL	Ref #2 Result mg/dL	VGG #1 Result mg/dL	VGG #2 Result mg/dL
	Date	Time	Patient	Species (C / F)	Gender	Other 1	Other 2	Samp. Type	Oper. Init.				
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													

Additional notes on any individual sample or patient: _____

Vet GlucoGauge Technical Support: 1-800-836-3837 24/7, 365 days/yr

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Results Analysis Sheet

1. List the reference results in order of INCREASING blood glucose values in the "Reference Result" column.
2. List the meter results associated with each reference result in the "Meter Result" column.
3. Perform the following calculation for each set of results and list them in their respective columns.

   3A) For reference results UNDER 75 mg/dL:

   (Meter result - reference result) = difference in mg/dL from reference

   3B) For reference results 75 mg/dL and HIGHER:

   (Meter result - reference result)/reference result x 100% = difference in % from reference
4. Indicate "yes" or "no" in the appropriate column that asks if difference is within the respective limits
5. Tally the "yes" and "no" answers below and compare to FDA guidelines

Result #	Reference Result	Meter Result	3A: UNDER 75 mg/dL Calculation	Within +/- 15 mg/dL of reference?	3B: 75 mg/dL and HIGHER Calculation	Within +/- 20% of reference?
1						
2						
3						
4						
5						
6						
7						
8						
9						
19						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Number of comparisons with reference result UNDER 75 mg/dL: _____

Number of the above comparisons within the +/- 15 mg/dL range: _____

At Least 95% of results within range? YES NO

Number of comparisons with reference result 75 mg/dL & HIGHER: _____

Number of the above comparisond within the +/- 20% range: _____

At Least 95% of results within range? YES NO