Gen Ultimate!®
4Pets

"Blood Glucose Monitoring System"

User Guide

dog **Cat**

157 mg/dL
mmol/L

MO 19 01-28 Day 10:26

Avantage!

PharmaTech Solutions

Thank you for selecting GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System.

This User Guide details proper usage of your GenUltimate!® 4Pets Avantage value priced blood glucose meter. Take note of warnings and cautions identified throughout this User Guide.

Please read this User Guide carefully before testing your blood glucose level.

Explains conditions for proper meter use and warns of potential damages to the system.

Useful information or notes.

*The above symbols have the meanings described.
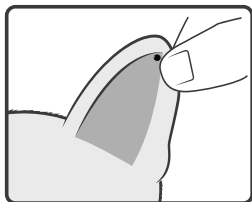
How to Perform a Blood Glucose Test

The following list summarizes the steps for
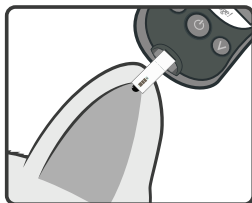checking your pets blood glucose level.

1.

The meter automatically turns on when you insert a test strip. The meter display will automatically switch to show a blinking icon of a drop of blood.

2.

Use a lancing device to obtain a small blood drop from your animal.

3.

Apply blood to the edge of the test strip to fill up the sample window. The blood will be automatically drawn into the test strip.

4.

The blood glucose value will appear on the display within five seconds.

GenUltimate!® 4Pets User Guide

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I. Product Description

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1. Precautions

- This is a medical device for in vitro diagnosis use for canines and felines only. Do not use this device to diagnose diabetes without the assistance of a veterinarian.

- Use this GenUltimate!® 4Pets Avantage blood glucose meter only with GenUltimate!® 4Pets glucose test strips.

- Carefully read over the instructions in this User Guide for the most accurate measurements.

- The GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System must be used with fresh blood collected from the capillaries. Using it with serum, plasma, artery or vein blood can result in inaccurate measurements.

- The GenUltimate!® 4Pets Avantage blood glucose test strips must be used within 180 days after opening the container.

- Never reuse test strips.

- The meter must be used at an operating temperature of 10-40º C in a place that is not humid. If temperature changes drastically, you should leave this monitoring system at room temperature for about 30 min before taking measurements.

- The measurements may be inaccurate if you touch the the narrow channel at the tip of the test strip with your hand or use a bent test strip.

- Do not use blood glucose test strips past their expiration date.

2. Cautions for Storage

- Store this product in a dry place at a temperature range of 5-30ºC and away from direct sunlight.

- Keep this product out of the reach of children.

I. Product Description

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3. GenUltimate!® 4Pets Blood Glucose Monitoring System

The GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System consists of the following components:

- GenUltimate!® 4Pets Avantage Blood Glucose Monitor
- Guide to GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System
- 30 GenUltimate! ® 4Pets Test Strips
- Test Strip Instructions

The GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System does not include:
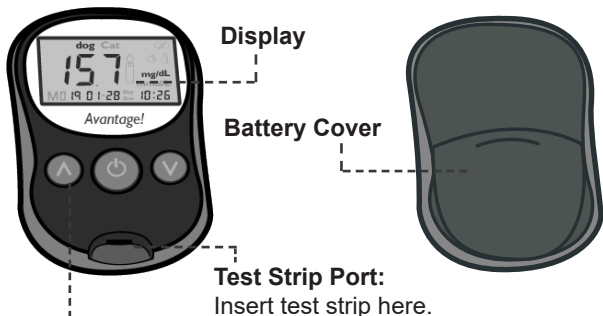
- 3V Battery (CR2032)

> i
> - Check the components after opening the packaging for GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System.
> - If any component is missing or damaged, do not use the system. Contact us and we will replace it with a new one.

I. Product Description

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4. GenUltimate!® 4Pets Avantage Blood Glucose Meter

[Front]   *[Back]*

Display

Battery Cover

Test Strip Port:
Insert test strip here.

Up and Down Button:
To Select or Change Settings

5. GenUltimate!® 4Pets Blood Glucose Test Strip

Edge to apply sample

Confirmation Window

Contact Bars
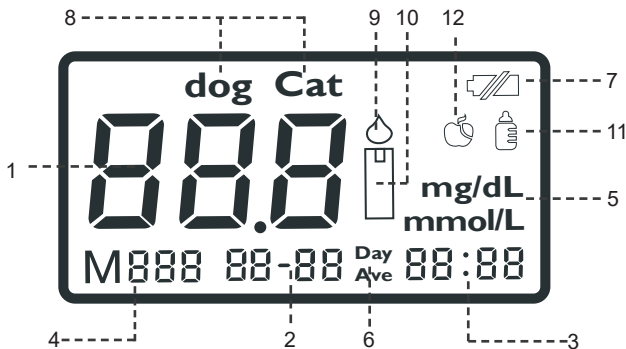Insert into the Test
Strip Port
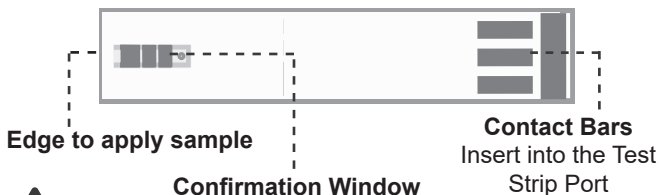
- Keep the meter and testing supplies out of the reach of children.
  Small objects such as the battery, the battery cover, test strips,
  lancets, protective covers and vial caps are choking hazards. Do
  not ingest or swallow any items.

I. Product Description

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6. GenUltimate!® 4Pets Avantage Blood Glucose Meter Display

888	1. Measurement Result	88-88	2. Measurement Date
88:88	3. Measurement Time	M888	4. Memory Number
mg/dL mmol/L	5. Unit of Measurement	Day Ave	6. Average Value
(battery icon)	7. Low Battery Level or Battery Replacement	dog Cat	8. Different Testing Settings
(drop icon)	9. Indication to apply Blood Sample	(strip icon)	10. Indication to apply Test Strip
(bottle icon)	11. Control Solution	(apple icon)	12. Before/After Meal

II. System Setting

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1. Turning on the Meter

Turn on the meter by pressing the power button in the front.
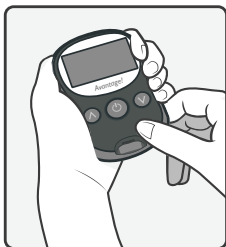
2. Setting the Date

Press and hold the ∧ button on the front of the monitor to enter the setting mode.

Year Setting:

Press ∧ or ∨ to change the year. When the correct year appears on the display, press the power button and move on to the next setting, "Month".

Month Setting:

Press ∧ or ∨ to change the month. When the correct month appears on the display, press the power button and move on to the next setting, "Day".

Day Setting:

Press ∧ or ∨ to change the day. When the correct day appears on the display, press the power button and move on to the next setting, "Time".

9

II. System Setting

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3. Setting the Time

1) First, change the hour setting.

2) Press the ∧ or v button to change
   the hour. Once the correct hour
   appears on the display, press the
   power button.

3) The hour is automatically saved
   and the minute value flashes next.

4) Press the ∧ or v button to change
   the minute. Once the correct
   minute appears on the display,
   press the power button and move
   on to the next setting, "Unit".

4. Setting the Unit of Measurements

1) Press ∧ or v to change the unit
   of measurement. When the
   desired unit appears on the
   display, press the power button
   to save the setting.

III. Starting Test Procedure

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Prepare the following to test your blood glucose.

- ◦ GenUltimate!® 4Pets Avantage Blood Glucose Meter
- ◦ GenUltimate!® 4Pets Blood Glucose Test Strip
- ◦ Lancing Device

⚠️

- The test strip container contains a desiccant that is harmful if inhaled or swallowed and may cause skin or eye irritation.

Set the Meter Code

Start with the meter power off. Insert a test strip to turn on the meter. Cat or dog will display; use the ∧ or ∨ to toggle between them. Refer to chart below.

| dog |

| Cat |

Species	GenUltimate!® 4Pets Avantage Meter
Canines	dog
Felines	Cat
Equines	Cat

III. Starting Test Procedure

/////////////////////////////

Insert the test strip and turn on the meter.

Take out one (1) test strip from the container and hold the meter as shown on the right. Insert the test strip all the way into the test strip port. You must not bend, cut or alter the test strip in any way. Use the test strip immediately after removing it from the container.

The code appears on the display. The blinking drop of blood icon indicates the meter is ready to test blood glucose.
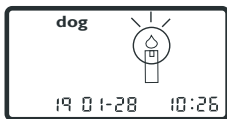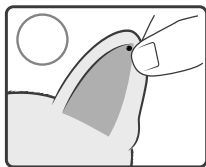
> - Blood glucose test strips are single-use products. Never reuse the same test strip for blood or glucose control solution.

IV. Measuring Blood Glucose

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1. Testing with an ear sample

1) Wash your hands and the test site with warm water and soap. Rinse and dry your hands thoroughly.

2) Use a sterile lancing device to collect a drop of blood from the test site.

3) Collect a drop of blood. Softly press or massage your pets ear until a round drop of blood is formed. If the blood smears or spreads, do not use the blood. Wipe the area and softly squeeze another drop of blood or collect blood from a different site.
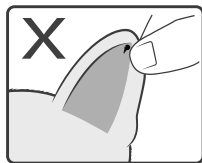
⚠️ - The lancet is a single-use product. Replace the protective cap and properly dispose of the used lancet.

IV. Measuring Blood Glucose

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2. Applying Blood and Reading Results

Once the blinking drop of blood icon appears on the display, you are ready to collect the blood sample. If the blinking drop of blood icon does not appear, remove the unused test strip and restart the testing process. (See pages 11-13)

1) **Obtain a blood sample:**
   Hold the ear and touch the edge of the test strip to the drop of blood.
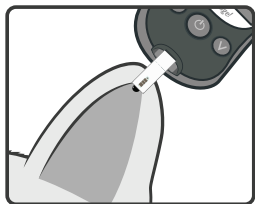
2) **Collect the blood sample:**
   Keep the tip of the test strip in contact with the blood until the confirmation window is filled with blood.

- *Do Not* apply blood to the top of the test strip.
- *Do Not* touch the edge of the test strip with your pets ear.
- *Do Not* smear or scrape the drop of blood with the test strip.
- *Do Not* apply more blood to the test strip after you have moved the drop of blood away.
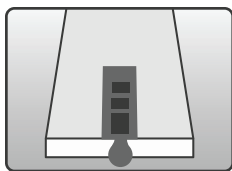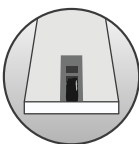- *Do Not* move the test strip in the meter during a test.
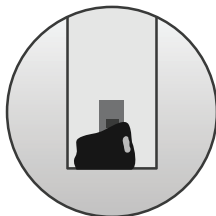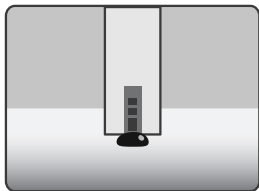
X

IV. Measuring Blood Glucose

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3) **Wait until the confirmation window is filled:**
   When the confirmation window is completely filled, a beep is heard
   and a five-second (5) countdown appears on the display. After five
   (5) seconds, the display shows the test results.
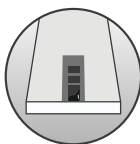
X   X   X

⚠️
  - If you remove the test strip during testing, the "**Er3**" message
    appears. Discard the test strip and re-start the test process.

4) **Check the result on the meter:**
   The blood glucose value appears
   on the display along with the unit of
   measurement, test date and time.
   The test results will be displayed for
   one (1) minute and automatically
   saved in the meter's memory.
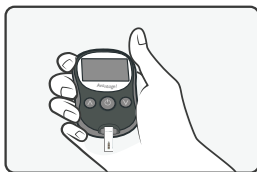
ℹ️
  - Always test with fresh capillary blood.

IV. Measuring Blood Glucose

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3. Unexpected Test Results

If the test result is higher or lower than expected, these are possible warning signs.

Dehydration and Low Blood Glucose Results

Serious dehydration due to excessive water loss can lead to incorrectly low test results. Contact your vet if your pet is exhausted due to excessive dehydration.

Low Blood Glucose Results

If the test result is below 30 mg/dL or "Lo" is displayed, it may indicate hypoglycemia (low blood glucose level). You may need to apply immediate treatment according to your vet's advice.

High Blood Glucose Results

If the test result exceeds 180 mg/dL or "Hi" is displayed, it may indicate hyperglycemia (high blood glucose level). You may need to apply immediate treatment according to your vet's advice.

Abnormal Red Blood Cell Results

If the hematocrit (percentage of red blood cells in blood) value is too high (over 50%) or too low (below 30%), the test result may be incorrect.

- The information provided here is for informational purposes only. Please check with a veterinarian/veterinary surgeon if you have health questions or concerns.

IV. Measuring Blood Glucose

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4. After Getting Blood Glucose Result

After reading the test result, remove the test strip to turn off the meter. You can enter memory mode and check your pet's blood glucose values stored in the meter.

<u>Disposal of Used Lancet and Test Strip</u>

The used lancet and test strip may be regarded as biologically hazardous wastes in your area. Please discard them appropriately in compliance with the regional regulations.
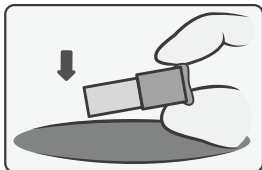
V. Memory Features

The GenUltimate!® 4Pets Avantage Blood Glucose Meter automatically saves 300 test results with date and time. If the memory is full, the oldest test result is automatically erased and the newest test result is saved.

You can check the average value of readings from the last 7, 14, and 30 days.

You don't have to set dates or times for average calculation.

The "Hi" or "Lo" values and the measurements using glucose control solution are not included in the calculation of averages.

> ⚠️
> - You are advised to record the test results with other relevant information such as time of insulin injections, exercise and diet for effective glucose management.

V. Memory Features

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1. Checking Previous Test Results

1) Press the power button to turn on the meter. Next, press the "∧" or "∨" button once. The meter is now in memory mode.

2) The result that shows first is the most recent test result. Press the "∨" button to view older test results and the "∧" button to view the more recent results.

```
         dog
 | 5 7          mg/dL
M001 01-28    10:32
```

3) After checking all the previous blood glucose test results, press the power button to turn off the meter.

4) If there is no saved test result on the meter, the display appears as shown on the right.

```
         Cat
 ─ ─ ─
M000
```

5) Press and hold the power button to clear the memory.

V. Memory Features

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6) When the meter is turned on press and hold the "∨" button until "Ave" and the codes appear. The meter can now display the average glucose value of the dog's last 7, 14, and 30 day tests. After that, every time you press the ∧ button, you can check the average result values for cat test for the last 7, 14 and 30 days. The values appear as shown on the right with the corresponding average value.

7) You can choose the range of tests by pressing the "∧" and "∨" buttons. The values appear as shown on the right with the corresponding average value.

8) If there are no test results saved in the memory you cannot check the average value. The display will appear as shown on the right.

```
 dog
 162    mg/dL
      Ave 7
```

```
 Cat
 ---
      Ave 7
```
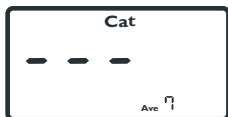
(i) - You cannot check previous test results or average values with a test strip inserted in the meter. Remove the test strip from the meter and turn off the meter first before pressing the "∧" or "∨" button.

VI. System Management

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GenUltimate!® 4Pets Avantage Blood Glucose Monitor System does not require special management.

<u>System Storage</u>

Store the components in a cool, dry place below 30°C. Do not keep them in a refrigerator. Avoid direct sunlight and heat. Immediately after using them, close the cap of the test strip and control solution container to prevent contamination. Always keep the test strips in the original container.

<u>Checking Expiration Date of Test Strips and Control Solution</u>

The expiration date of the test strip and control solution is printed on the container labels. When you open the test strip vial or control solution container for the first time, you should record the discard date for discarding (3-6 months after opening the container) on a blank space on the container label.

- Products whose expiration date or discard date has passed can lead to inaccurate test results.

<u>Meter Cleaning</u>

Clean the meter by wiping its outer surface with a damp cloth and gentle detergent. Do not use alcohol or other liquids to clean the meter. Take special care not to let liquid, foreign substances, dust, blood, or control solution get into the meter through the test strip port. Do not spray detergent on or immerse the meter in sterilization solution.

VI. System Management

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Battery (Sold Seperately)

GenUltimate!® 4Pets Avantage Blood Glucose Meter uses one 3.0V lithium battery (CR2032). The meter is not supplied with a battery, seperate purchase is necessary. When the battery icon appears on the top right, it means the battery level is low.

After the battery icon first appears, you can perform at least 100 tests.
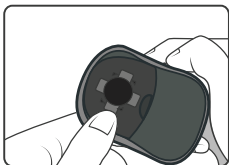
If the battery icon blinks, it means no more tests can be performed. In this case, replace the battery with a new one.
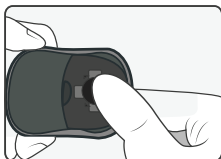
Replacing Battery

1) With the meter turned off, open the battery cover and remove the used battery.

VI. System Management

///////////////////////////////

2) Insert a new battery with the "+" side toward the user. Push it inside until it clicks into place. Fix the battery cover to its original position.

- If the meter does not power on even after replacing the battery, check the battery again to see if the "+" side is up.

3) Set the date and time again by referring to the system settings in pages 9-10.

4) Discard the used batteries in accordance with the regulations in your local area.

- Even if you remove the battery, the saved test results are not affected. However, you need to set the date and time again.

VII. Errors and Messages

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Inappropriate meter use can cause inaccurate results that do not generate warning messages. Therefore, carefully read this User Guide before using the meter.

Message	*Meaning*
Lo	Your pet's blood glucose level may be very low, maybe below 20 mg/dL (serious hypoglycemia).Retest your pet's blood glucose level. If you get the same results, even after repeated tests, consult with your veterinarian/veterinary surgeon.
HI	Your pet's blood glucose level may be very high, possibly above 500mg/dL or 750mg/dL (serious hyperglycemia). Retest your pet's blood glucose level. If the result appears "Hi" again, you should follow the directions of your veterinarian/veterinary surgeon.
Er 1	The meter is being used outside the temperature range for measurement (10-40°C) Stabilize the meter for 30 min to the preferred operating temperature before retesting.
Er 2	This error occurs when you insert a used test strip into the meter or the test strip is damaged. Use a new test strip and try again.

VII. Errors and Messages

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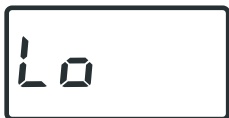
Message	*Meaning*
$Er\ 3$	This error occurs when the test strip is removed during a test. When the ER3 message appears, the meter will beep and powers off after 3 seconds. Try again with a new test strip.
$Er\ 4$	This error occurs when the blood touches the test strip before the measurement code is selected. Try again with a new test strip.
$Er\ 5$	This error occurs when there is not enough blood on the strips. Try again with new test strip.
Cat − − − M000	The meter has no saved test results.

VII. Errors and Messages

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Message	*Meaning*
⟍	When the battery icon blinks it means that the battery level is too low for performing a test or showing previous results. Replace the battery with a new one.
dog **157** mg/dL M001 01-28 10:32	The test result saved in the meter is shown. For details, see pages 19-20.
dog **162** mg/dL Ave 1	You can check the average values from the test results saved on the meter. For details, see pages 19-20
Cat - - - Ave 1	You cannot check the average values of the test results because there is no saved data on the meter.
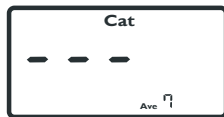
VIII. Product Specifications

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Product Name	GenUltimate!® 4Pets Avantage Blood Glucose Meter
Measurement Range	20~500mg/dL (Human) 20~750mg/dL (Cat, dog)
Calibration Method	Plasma Calibration
Sample Type	Fresh Capillary Blood (Whole Blood)
Sample Amount	Min. 1 uL
Measurement Time	5 sec
Measurement Method	Glucose Oxidase
Measurement Unit	mg/dL or mmol/L
Meter Power	One replaceable 3V lithium battery (CR2032)
Battery Life	Continuous measurements for about 1,000 times
Memory Capacity	300 blood glucose test results
Size and Weight	5.4 x 8.7 x 1.9cm, about 48g (including battery)
Operation Range	Temperature: 10-40°C, Relative Humidity: 20-80% Altitude: Max. 3,000m Hematoric: 30-50%
Power Off	The meter turns off automatically if no action is taken for one (1) minute.
Test Strip Storage Conditions	Temperature: 5-30 °C, Relative Humidity: 20-80%

IX. Technical Information

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Accuracy and Precision Data

PERFORMANCE CHARACTERISTICS:

The performance of the GenUltimate!® 4Pets Test Strips has been tested in laboratory studies. The testing range of the GenUltimate!® 4Pets Avantage Blood Glucose Monitoring System is 30 to 600 mg/dL (1.7 to 33.3 mmol/L).

PRECISION AND ACCURACY OF GENULTIMATE!® 4PETS TEST STRIPS:

Laboratory performance (accuracy and precision) of the GenUltimate!® 4Pets test strips in the labeled species was studied in venous blood samples. Results were compared with those obtained using the YSI Glucose Analyzer or AlphaTRAK®2 test results.

PRECISION:

Measurement range: 40 – 440 mg/dl (2.2 – 24.4 mmol/L)
Precision: Precision was evaluated with six glucose levels in whole blood. Results show strip-to-strip variability in blood tests of 3.7% or less.

Within-Run Precision:

Average Glucose Concentration	mg/dL	47	70	116	180	288	402
Code dog	CV%	3.7%	4.6%	2.9%	2.7%	2.4%	2.1%
Average Glucose Concentration	mg/dL	51	69	122	183	285	410
Code Cat	CV%	4.3%	2.7%	2.5%	2.1%	2.2%	1.9%

IX. Technical Information

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ACCURACY:

Capillary blood glucose results were compared with those obtained using the YSI Glucose Analyzer or AlphaTRAK®2. These regression statistics are derived from a plot of the blood glucose data versus data from the comparative method:

GenUltimate!® 4Pets	Code dog	Code Cat
Slope	1	0.994
y-intercept	0.9	2.09
Correlation coefficient (R)	0.9938	0.9955
Number of samples tested	240	240
Range tested	47~402 mg/dL	51~410 mg/dL

AlphaTrak code 36 VS 4Pets dog code

AlphaTrak code 38 VS 4Pets Cat code
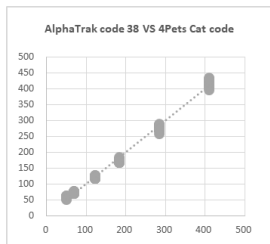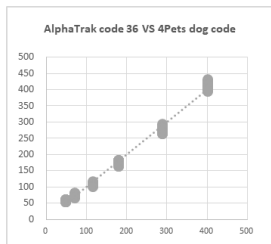
This study shows that the GenUltimate!® 4Pets test strip performance compares well with a laboratory method.

Gen Ultimate!® 4Pets

"Blood Glucose Monitoring System"

PharmaTech Solutions