



## GenUltimate!® 4Pets Test Strips Instructions

GenUltimate!® 4Pets Blood Glucose Test Strips product information for use only with the GenUltimate!® 4Pets Advantage Blood Glucose Meter to test for glucose in whole blood in dogs, cats, and horses.

**IMPORTANT:** Please read this entire pamphlet before using GenUltimate!® 4Pets Test Strips to test an animal's blood glucose level. Failure to follow instructions could cause incorrect results. Please follow a veterinarian/veterinary surgeon's direction on frequency of testing and time of day for testing.

### INTENDED USE:

The GenUltimate!® 4Pets Blood Glucose Test Strips are used with GenUltimate!® 4Pets Advantage Blood Glucose Meters only. The GenUltimate!® 4Pets Test Strips are designed to use coulometric technology to measure glucose (sugar) in whole blood. The GenUltimate!® 4Pets Test Strips are for testing outside the body (in vitro diagnostic use) and in the home or other remote settings to monitor blood glucose levels in dogs, cats, and horses.

**CAUTION:** The GenUltimate!® 4Pets Test Strips are not intended for human blood glucose testing and may give erroneous results when used in humans.

**WARNING:** Any change in medication, based on the GenUltimate!® 4Pets blood glucose test results, without the consent and advice of a veterinarian/veterinary surgeon, is not recommended.

### PRECAUTIONS:

- » Keep the test strip away from children. The cap is a choking hazard. The cap or vial contains drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.
- » If the OneTouch® Ultra® Control Solution test result falls outside the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the GenUltimate!® 4Pets Advantage glucose meter may not be working properly.
- » **DO NOT** use the system to test an animal's blood glucose until a control solution test result is obtained that is within the recommended range. The recommended control solution range is printed on the test strip vial.
- » Sample should touch only the tip of the test strip. Once the tip of the test strip is touched to sample, do not allow the strip to come into contact with blood.
- » For *in vitro* diagnostic use (outside the body) only.
- » All devices contaminated with blood should be disposed of properly.
- » **DO NOT** use the test strips beyond the expiry date printed on the package since this may cause inaccurate results. Check for the expiry date on the side of the test strip vial prior to use.
- » Low or high blood glucose readings can indicate a potentially serious medical condition. If the blood glucose reading is unusually low or high repeat the test with a new test strip. If the reading is not consistent with any visible symptoms or if the blood glucose level is less than 65 mg/dL (3.6 mmol/L) or higher than 250 mg/dL (13.9 mmol/L) for dogs, cats, and horses<sup>1</sup>, contact a veterinarian/veterinary surgeon.

### STORAGE AND HANDLING:

- » Store test strips in a cool, dry place between 40°F - 86°F (4°C - 30°C). Do not refrigerate. Do not freeze. Do not expose to direct sunlight or heat. Extreme temperatures or humidity may cause inaccurate readings.
- » Store away from direct sunlight and heat.
- » Use each strip immediately after removing it from the vial.
- » Store Test strips in their original vial only. The cap or vial contains drying agents to protect the test strips. **DO NOT** transfer the test strips to a new vial or any other container.
- » After removing a test strip from the vial, replace the vial cap immediately and close it tightly.
- » The "Discard date" is 90 days after you first open a vial. Write this number on the vial. Discard any unused test strips after that date.
- » Each box of test strips has an expiration date printed on it. Do not use test strips beyond the expiration date.
- » **Never** bend, cut, damage, or change the test strips in any way.
- » Use each test strip only once. Never reuse a test strip that has blood or control solution on it.
- » After doing a test do not return the test strip to the vial.
- » Use clean, dry hands to gently touch the test strip when removing it from the vial or inserting it into the meter.

### HOW TO PERFORM THE TEST:

See the *GenUltimate!® 4Pets Advantage Blood Glucose Monitoring System User Guide* for a detailed guide on how to perform the test and select the proper test codes.

- » Be sure that the correct code is displayed on the meter screen. If the code does not match, press the "▲" button, then scroll up or down to the correct code by pressing the "▲" or "▼" button on meter.
- » Check meter and test strip performance regularly using the OneTouch® Ultra® Control Solution

#### Step #1) Set Up:

Insert a test strip into the meter like in **Diagram A**. The meter will automatically turn on. Enter the appropriate CODE for the species being tested, as identified in the table below, or on the strip vial.

Species	GenUltimate!® 4Pets Advantage Meters
Canines	dog
Felines	Cat
Equines	Cat



Diagram A

**NOTE:** Use appropriate code recommended for each species in the table above.

#### Step #2) Perform the Test:

Please use standard sampling techniques for obtaining blood in all species. Refer to the GenUltimate!® 4Pets Advantage Blood Glucose Monitoring System User Guide or veterinarian/veterinary surgeon for blood sampling instructions. When the prompt to apply the sample appears on the screen, lance the site chosen, and obtain a blood sample about the size of a pinhead (0.3 microlitres of blood) as shown in **Diagram B**. Gently touch only the tip of the test strip to the blood sample. The test strip may be filled from either side, but not both sides. When the strip is full, the meter will "beep" or you will see the moving lines on the display. **DO NOT** press the edge of the strip against the test site. **DO NOT** put the sample on top of the sample target area. If you have a problem filling the test strip, see the Customer Service section below for your customer service options.



Diagram B

#### Step #3) Read Results:

Results are displayed in approximately 5 seconds. The test time may vary depending on the blood glucose level. The results will be stored in the meter memory. Results are displayed as mg/dL (milligrams per decilitre) or in mmol/L (millimole per litre).

### LO GLUCOSE VALUES:

GenUltimate!® 4Pets Advantage Meters display results between 20 to 500 mg/dL (1.1 to 27.75 mmol/L) or 20 to 750 mg/dL (1.1 to 41.62 mmol/L) depending on the version of the meter. If the test result is lower than 20 mg/dL (1.1 mmol/L), "LO" (Low) will appear on the meter display. This indicates severe low blood glucose (hypoglycemia).

**For dog and cat use at home, treat low blood glucose immediately as recommended by a veterinarian/veterinary surgeon.**

### HI GLUCOSE VALUES:

The result "HI" (High) will appear on the screen if the blood glucose reading is above 500 mg/dL or 750 mg/dL (27.75 mmol/L or 41.7 mmol/L). This indicates severe high blood glucose (hyperglycemia).

**For dog and cat use at home, treat high blood glucose immediately as recommended by a veterinarian/veterinary surgeon.**

### UNEXPECTED RESULTS:

Low or high blood glucose readings can indicate a potentially serious medical condition. If the blood glucose level is unusually low or high, or if the animal does not show symptoms consistent with the results, repeat the test with a new test strip. If the reading is not consistent with any symptoms, or if the blood glucose result is less than 65 mg/dL (3.6 mmol/L) or higher than 250 mg/dL (13.9 mmol/L) for dogs, cats, and horses, we recommend you contact a veterinarian/veterinary surgeon.

### LIMITATIONS:

The GenUltimate!® 4Pets Test Strips give accurate results when the following limitations are observed:

- » Use each test strip only once. **DO NOT** reuse test strips.
- » Hands and test site must be clean and dry prior to testing.
- » Use fresh, whole blood from the site selected to test.
- » There is no effect from altitude up to 9,996 feet (3,046 meters) above sea level.

### ONETOUCH® ULTRA® GLUCOSE CONTROL SOLUTION:

For use with the GenUltimate!® 4Pets Advantage Blood Glucose Monitoring System to ensure that the GenUltimate!® 4Pets Advantage Meter and GenUltimate!® 4Pets Test Strips are working properly.

**WARNING AND PRECAUTIONS:** Always store the control solution at room temperature between 36°-86°F (2°-30°C). **DO NOT** freeze. The control solution can be used for up to 3 months of first opening the bottle or until the expiry date, whichever comes first. Replace the cap on the control solution bottle and close tightly immediately after use. **DO NOT** dilute the control solution with water or any other liquid. **DO NOT** take internally. If swallowed, seek medical advice immediately. Control solution tests are specified to be accurate only when used between 59°-104°F (15°-40°C).

### DESCRIPTION:

Glucose control solution allows performance of quality control tests to ensure that the GenUltimate!® 4Pets Advantage Blood Glucose Monitoring System is working properly and that the test results are reliable.

For detailed instructions on how to perform a control solution test, please consult the *GenUltimate!® 4Pets Advantage Blood Glucose Monitoring System User Guide*. The control solution contains a fixed amount of glucose.

### CHECKING THE SYSTEM:

The control solution is used to check the performance of the GenUltimate!® 4Pets Advantage Meter, GenUltimate!® 4Pets Test Strips, and testing technique. The system is performing correctly if the control solution test result falls within the specific control solution ranges listed on the PetUltimate!® Test Strip vial.

### A CONTROL SOLUTION TEST SHOULD BE PERFORMED:

- After setting up the meter and before the first blood test
- If the blood glucose results are questionable and require confirmation that the meter and test strips are working properly together
- When a new vial of test strips is opened
- If the test strip vial was not closed properly
- If the blood glucose meter is dropped.
- Upon advice of a veterinary professional

Performing a control solution test requires a GenUltimate!® 4Pets Advantage Meter, GenUltimate!® 4Pets Test Strips and OneTouch® Ultra® Control Solution. A control solution test follows exactly the same procedure as a test with a drop of blood. Invert the control solution before use. Place a drop onto a clean surface such as the cap of the control solution vial. Gently touch one edge of the test strip to the control solution as in **Diagram C**. The recommended control solution range for dogs, cats, and horses is printed on the test strip vial. Ensure that the control solution test result is within the range printed on the test strip vial. If the test result is within the range printed on the test strip vial, the meter and test strips are working properly.

### Potential causes for results outside of the control ranges:

- The correct test procedure may not have been followed.
- The meter code is set incorrectly. Enter the correct code from the test strip vial or from the control solution package insert.
- The test strip may have been exposed to too high or too low a temperature. Repeat the test using an undamaged test strip.
- The test strips may have passed their expiry date. If the test strips have expired, discard them. Repeat the test using a test strip from a new batch, which has not reached its expiry date.
- The control solution may have expired or may have been diluted. Repeat the test with new control solution.
- Control solution may be dried on the tip. Remove the control solution cap and wipe tip with tissue.
- Control solution test performed outside of the acceptable temperature range of 59°-104°F (15°-40°C).



Diagram C

If all these possibilities have been ruled out and the test result is still outside the specified range, call GenUltimate!® 4Pets customer support at 1-844-874-2762.

**DO NOT** use the blood glucose monitoring system to test the animal's blood glucose if the control solution test results are outside the recommended range.

### PERFORMANCE CHARACTERISTICS:

The performance of the GenUltimate!® 4Pets Test Strips has been tested in laboratory studies. The testing range of the GenUltimate!® 4Pets Advantage 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.

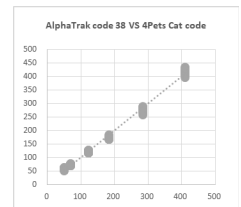
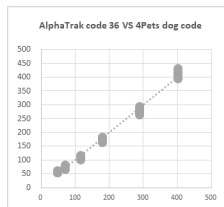
### Within-Run Precision:

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%

### 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



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

### CUSTOMER SERVICE:

It is our goal to provide you with accurate glucose testing products and exceptional customer service. If you are not satisfied with this product, or need any assistance with the product, please contact your authorized GenUltimate!® 4Pets representative specified on the outer packaging or PharmaTech Solutions Customer Support at 1-833-737-7387.

GenUltimate!® 4Pets test strips are a product of PharmaTech Solutions, Inc. and are not manufactured, distributed, endorsed, or approved by nor associated with LifeScan®, Inc. a Johnson & Johnson® Company, manufacturers and distributors of the OneTouch® Ultra® Family of Meters and OneTouch® Ultra® test strips. OneTouch®, Ultra®, Ultra®2 and LifeScan® are registered trademarks of Johnson & Johnson® Company. GenUltimate!® 4Pets is a registered trademark of PharmaTech Solutions, Inc.

### CHEMICAL COMPOSITION OF TEST STRIPS:

	GenUltimate!® 4Pets	WT %
1.	Glucose Oxidase (From Aspergillus Niger)	≤ 3 IU
2.	Potassium Ferricyanide	≤ 5 mg
3.	Other Ingredients Such As Buffer	≤ 0.1 mg

	Consult instructions for use
	Temperature limitation
	Do not re-use
	In vitro diagnostic medical device

	Manufactured by
	Batch code
	Use by expressed as CCYY-MM-DD

1. Ettinger SJ, Feldman EC. Textbook of Veterinary Internal Medicine. Vol 2. WB Saunders Company, pp 1529-1534. 1995.  
2. Data on file

GenUltimate!® 4Pets Test Strips are manufactured for and distributed by: PharmaTech Solutions, Inc. Westlake Village, CA 91361 USA

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