

AlphaTRAK 2

BLOOD GLUCOSE TEST STRIPS

AlphaTRAK 2 Blood Glucose Test Strips product information for use only with the AlphaTRAK 2 Blood Glucose Meter to test for glucose in whole blood in dogs and cats.

Important: Please read this information and the *AlphaTRAK Blood Glucose Monitoring System User Guide* before using the AlphaTRAK 2 Test Strips to test an animal's blood glucose level. Failure to follow instructions will cause incorrect results. Please follow a veterinarian/veterinary surgeon's direction on frequency of testing and time of day for testing.

Intended Use

The AlphaTRAK 2 Blood Glucose Test Strips are used with AlphaTRAK 2 Blood Glucose Meters only. The AlphaTRAK 2 Test Strips and meter are designed to use coulometric technology to measure glucose (sugar) in whole blood.

The AlphaTRAK 2 Test Strips are for testing outside the body (*in vitro* diagnostic use).

The AlphaTRAK Blood Glucose Monitoring System is intended for use in a veterinary and medical professional setting to monitor blood glucose levels in dogs and cats. It is also intended for use in the home setting to monitor blood glucose levels in dogs and cats.

Caution: The AlphaTRAK 2 Blood Glucose 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 AlphaTRAK blood glucose test results, without the consent and advice of a veterinarian/veterinary surgeon, is not recommended.

AlphaTRAK System components for blood glucose testing

- AlphaTRAK 2 Meter - AlphaTRAK 2 Test Strips - AlphaTRAK Lancets
- *AlphaTRAK Blood Glucose Monitoring System User Guide* - AlphaTRAK Control Solution - Lancing Device

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 AlphaTRAK 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 AlphaTRAK 2 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 in the control solution package insert and is also on the test strip vial for dogs and cats.

Sample should touch only one side of the test strip. Once one side of test strip is touched to sample, do not allow other side 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. Veterinary professionals should follow their institution's infection control protocols.

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 and cats¹, contact a veterinarian/veterinary surgeon.

Storage and Handling

- Store the test strip package in a dry place between 40° - 86°F (4° - 30°C). Use test strips only within the system operating temperature range as outlined in the *AlphaTRAK Blood Glucose Monitoring System User Guide*.
- 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 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.
- Do not** bend, cut or alter a AlphaTRAK 2 Test Strip in any way.
- Use clean, dry hands to gently touch the test strip when removing it from the vial or inserting it into the meter.
- If you accidentally prick yourself with a lancet, please follow normal first aid procedures. If bleeding persists, please contact your local healthcare professional.

How to Perform the Test

See the *AlphaTRAK Blood Glucose Monitoring System User Guide* for a detailed guide on how to perform the test and select the proper test code.

- Only use the AlphaTRAK 2 Meter with AlphaTRAK 2 Blood Glucose Test Strips.
- Be sure that the correct code is displayed on meter screen. If the code does not match, press the “c” button, then scroll up or down to the correct code by pressing the “c” or “m” button on meter.
- Check meter and test strip performance regularly using the AlphaTRAK Control Solution.

1. Set Up

Insert a test strip into the meter. 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.

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

Species	CODE for AlphaTRAK 2 Meter (Purple Meter)
CAT	See code identified on the vial
DOG	See code identified on the vial

2. Perform the Test

Please use standard sampling techniques for obtaining blood in all species. The AlphaTRAK Lancet may be used to obtain the correct size blood sample. Refer to the *AlphaTRAK 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).

Gently touch only one edge 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.

3. Read Results

Results are displayed in an average of 15 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) in the USA or in mmol/L (millimole per litre) or mg/dL outside the USA.

Target Glucose Values

For dog and cat use at home, consult a veterinarian/veterinary surgeon for the target glucose values for each species. For Veterinary Professionals: results should be interpreted in accordance with the standards of your practice.

LO Glucose Values

AlphaTRAK 2 Meters display results between 20 to 750 mg/dL (1.1 to 41.7 mmol/L). 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 (hypoglycaemia).

For dog and cat use at home, treat low blood glucose immediately as recommended by a veterinarian/veterinary surgeon. For Veterinary Professionals: results for dogs and cats should be interpreted in accordance with the standards of your practice.

HI Glucose Values

The result “HI” (High) will appear on the screen if the blood glucose reading is above 750 mg/dL (41.7 mmol/L). This indicates severe high blood glucose (hyperglycaemia).

For dog and cat use at home, treat high blood glucose immediately as recommended by a veterinarian/veterinary surgeon. For Veterinary Professionals: results for dogs and cats should be interpreted in accordance with the standards of your practice.

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 and cats¹, contact a veterinarian/veterinary surgeon.

Limitations

The AlphaTRAK 2 Test Strips give accurate results when the following limitations are observed.

- The test strips are for single use only. **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 10,400 feet (3,170 metres) above sea level.

Additional Information for Veterinary Professionals

- A venous whole blood sample may also be used. Use venous blood within 10 minutes after drawing. Common anticoagulants (potassium oxalate, heparin, EDTA) may be used.
- In situations of decreased peripheral blood flow, results from capillary sampling may not represent the true physiological state. Examples would include but are not limited to: dehydration, hypotension or shock. Critically ill patients should not be tested with home use blood glucose meters.

AlphaTRAK Glucose Control Solution

For use with the AlphaTRAK Blood Glucose Monitoring System to ensure that the AlphaTRAK 2 Meter and AlphaTRAK 2 Test Strips are working properly.

Warnings 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 AlphaTRAK 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 *AlphaTRAK 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 AlphaTRAK 2 Meter, AlphaTRAK 2 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 AlphaTRAK 2 Test Strip vial or package insert.

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 blood glucose meter is dropped.
- If the test strip vial was not closed properly.
 - Upon advice of a veterinary professional.

Performing a control solution test requires an AlphaTRAK 2 Meter, AlphaTRAK 2 Test Strips and AlphaTRAK Control Solution. A control solution test follows exactly the same procedure as a test with a drop of blood. Insert the control solution before use. Gently touch one edge of the test strip to the control solution. The recommended control solution range for dogs and cats is printed on the test strip vial. Ensure that the control solution test result is within the range printed on the test strip vial or package insert. If the test result is within the range printed on the test strip vial or package insert, the meter and test strips are working properly.

Species	Control Solution Ranges (Purple Meter)
Cats	100-185 mg/dL (5.5-10.27 mmol/L)
Dogs	111-205 mg/dL (6.1-11.38 mmol/L)

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).

If all these possibilities have been ruled out and the test result is still outside the specified range, call Zoetis Inc. at 1-888-963-8471.

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.

Contents

Each bottle containing 4.0 ml AlphaTRAK Glucose Control Solution contains:

- D-Glucose
- FD&C red dye
- Preservative
- Viscosity-adjusting agent

Performance Characteristics

The performance of the AlphaTRAK 2 Test Strips has been tested both in laboratory and clinical studies. The testing range of the AlphaTRAK Blood Glucose Monitoring System is 20 to 750 mg/dL (1.1 to 41.62 mmol/L).

Performance and Accuracy of AlphaTRAK 2 Meter

The clinical performance (accuracy and precision) of the AlphaTRAK 2 Blood Glucose Meter in the labelled species was studied in venous samples obtained from diseased and non-diseased clinical animals.

Results are as follows²:

Species	No. Samples Tested	Reference Comparator	Average Bias to Reference (%)	Average Coefficient of Variation (%)	Reference Range of Samples Tested
Dog	54	Antech	0.1	5.2	93-607 mg/dL (5.2-33.69 mmol/L)
Cat	50	Antech	-1.6	5.3	82-497 mg/dL (4.6-27.59 mmol/L)

Chemical Composition of Test Strips

FAD Glucose Dehydrogenase (*Aspergillus Oryzae*) ≥ 1.0 Unit

Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

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

Symbols

	Consult instructions for use		Manufactured by
	Temperature limitation		Batch code
	Do not re-use		Use by expressed as CCYY-MM or CCYY-MM-DD
	<i>in vitro</i> diagnostic medical device		Serial number
	Sterilised using radiation		Catalogue number

For Customer Care call 1-888-963-8471.

Pour joindre le service à la clientèle composer le 1-888-963-8471.

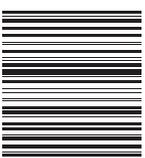
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