

# AlphaTRAK™

## BLOOD GLUCOSE MONITORING SYSTEM

AlphaTRAK Blood Glucose Monitoring Test Strips product information for use with the AlphaTRAK Blood Glucose Meter to test for glucose in whole blood in dogs, cats, ferrets, horses, rats and mice.

**Important:** Please read this information and the *AlphaTRAK Blood Glucose Monitoring System User Guide* before using the AlphaTRAK 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. **Federal law (USA) restricts this device to use by or on the order of a licensed veterinarian. Veterinary medical device for use under the direction of a veterinary professional.**

### Intended Use

The AlphaTRAK Blood Glucose Test Strips are used with the AlphaTRAK Blood Glucose Meter only. The AlphaTRAK test strips and meter are designed to use coulometric technology to measure glucose (sugar) in whole blood. The AlphaTRAK 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, cats, ferrets, horses, rats and mice. Also, intended for use in the home setting to monitor blood glucose levels in dogs and cats.

**Warnings:** 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 glucose testing

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

**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 glucose meter may not be working properly.

**Do not** use the system to test an animal's blood until a control solution test result is obtained that is within the recommended range. The recommended control solution range is on the package insert and also on the test strip vial for dogs and cats.

**Do not** fill the test strip from both the left and right sample target areas during a single test. This may cause inaccurate test results.

### Precautions

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 expiration date printed on the package since this may cause inaccurate results.

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 cats<sup>1</sup>, contact a veterinarian/veterinary surgeon and follow his or her treatment advice.

### Storage and Handling

- Store the test strip package in a dry place between 39° - 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 Test Strip in any way.
- Use clean, dry hands to gently touch the test strip anywhere 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

#### 1. Set Up

Put a strip in the meter. Press the "m" button to turn the meter on.

Make sure the code matches the code printed on the test strip vial label for dogs and cats, and package insert for ferrets, horses, rats and mice. If the code does not match, see the *AlphaTRAK Blood Glucose Monitoring System User Guide* for how to code the meter.

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

Species	CODE Recommendation
CAT	See AlphaTRAK Test Strip Vial for CODE CAT.
DOG	See AlphaTRAK Test Strip Vial for CODE DOG.
FERRET	CODE 7
HORSE	CODE 5
MICE	CODE 7
RAT	CODE 7

#### 2. Perform the Test

Please use standard sampling techniques for obtaining blood. For dogs, cats and ferrets the AlphaTRAK lancet may be used to obtain the correct size blood sample. For dogs and cats, refer to the *AlphaTRAK Blood Glucose Monitoring System User Guide* or veterinarian/veterinary surgeon for blood sampling.

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.

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 moving lines/ arrows will be seen 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 deciliter) in USA and outside the USA results are displayed in mmol/L (millimole per liter).

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

- Use only the AlphaTRAK Blood Glucose Meter with AlphaTRAK Blood Glucose Test Strips.
- Be sure that the code on the meter display screen matches the recommended code on the test strip vial for dogs or cats, and the package insert for ferrets, horses, rats and mice. If it does not match, see the *AlphaTRAK Blood Glucose Monitoring System User Guide* for how to code the meter.
- Fill the strip from only one side of the test strip.
- The test strips are for single use only. **Do not** reuse test strips.
- Do not** use test strips that are beyond their expiration date. Check the test strip vial for the discard date.
- Avoid exposing test strips to extreme temperatures.
- Check meter and test strip performance regularly using the AlphaTRAK Control Solution.
- Blood glucose test results are shown on the meter as mg/dL (USA) or mmol/L (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 animal. For Veterinary Professionals: Results should be interpreted in accordance with the standards of your practice.



### LO Glucose Values

The AlphaTRAK Meter displays results between 20 and 750 mg/dL (1.1-41.7 mmol/L). If the test result is lower than 20 mg/dL (1.1 mmol/L), "Low" (LO) will appear on the meter display. This indicates severe low blood glucose (hypoglycemia/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 ferrets, horses, rats and mice should be interpreted in accordance with the standards of your practice.**

### HI Glucose Values

If the test result is above 750 mg/dL (41.7 mmol/L), "High" (HI) will appear on the meter display screen. This indicates severe high blood glucose (hyperglycemia/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 ferrets, horses, rats and mice 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) and higher than 250 mg/dL (13.9 mmol/L) for dogs and cats<sup>2</sup>, contact a veterinarian/veterinary surgeon and follow his or her treatment advice.

### Limitations

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

- The test strips are for single use only. **Do not** reuse test strips.
- Clean the site and dry thoroughly before testing.
- Use fresh, whole blood from the site selected to test.
- There is no effect from altitude up to 10,400 feet (3,170 meters) 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.
- The injection of solutions containing dextrose will produce elevated blood glucose levels.
- 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 Meter and AlphaTRAK Test Strips are working properly.

**Warnings and Precautions:** Always store the control solution at room temperature (between 50° - 86° F or 10° - 30° C). **Do not** freeze. The control solution can be used for up to 3 months of first opening the bottle or until the expiration 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.

### Contents

Each bottle containing 4.0 ml AlphaTRAK Glucose Control Solution contains:

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

### Checking the System

The control solution is used to check the performance of the AlphaTRAK meter, 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 Test Strip vial or package insert.

### A control solution test should be performed

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

Performing a control solution test requires an AlphaTRAK Meter, AlphaTRAK Test Strips, and AlphaTRAK 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. 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, the meter and test strips, or package insert are working properly.

Species	Control Solution Ranges
Cats	108-162 mg/dL (6.0-9.0 mmol/L)
Dogs	123-185 mg/dL (6.8-10.3 mmol/L)
Ferrets	129-193 mg/dL (7.2-10.7 mmol/L)
Horses	106-158 mg/dL (5.9-8.8 mmol/L)
Mice	129-193 mg/dL (7.2-10.7 mmol/L)
Rats	129-193 mg/dL (7.2-10.7 mmol/L)

- Repeat the test to confirm the result.
  - The correct test procedure may not have been followed.
  - The code set in the meter may not match the test strip code.
  - 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 expiration 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 expiration date.
  - The control solution may have expired or may have been diluted.
  - Control Solution test performed outside 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 Abbott Animal Health Customer Care (USA and Canada) at (888) 299-7416 or Technical Enquires (UK) at + 44 (0) 1628 644354. **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 AlphaTRAK 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 41.7 mmol/L).

### Performance and Accuracy

The clinical performance (accuracy and precision) of the AlphaTRAK blood glucose meter in the labeled species was studied in venous samples obtained from diseased and non-diseased clinical animals. Results are as follows<sup>2</sup>:

Species (Strain)	No. Samples Tested	Reference Comparator	Average Bias to Reference (%)	Average Coefficient of Variation (%)	Reference Range of Samples Tested (mg/dL)
Dog	236	Antech Labs	1.4	ND <sup>a</sup>	42-594
	15	Antech Labs	6.0	2.6	439-647
Cat	232	Antech Labs	-0.71	ND <sup>a</sup>	51-509
	30	Antech Labs	-2.0	2.2	58-769 <sup>b</sup>
Horse-Adult	49	Antech Labs	-6.0	1.5	92-216
Horse-Foal	49	Antech Labs	-3.0	1.9	49-287
Ferret	18	Antech Labs	9.7	4.9	33-204
Mouse (C57, db-db, db-lb)	47	AEROSSET	-3.8	3.1	17-1071
	45	AEROSSET	-2.4	1.9	199-789
Rat (CD, ZDF)	42	AEROSSET	-3.2	1.8	28-798

<sup>a</sup> ND=not determined

<sup>b</sup> Extended range validated in cat with *in vitro* testing in feline blood spiked with dextrose or degraded with heat to obtain samples throughout the range.

### Chemical Composition of Test Strips

PQQ Glucose Dehydrogenase ≥ 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 Abbott Laboratories.

For Customer Care (USA and Canada) call (888) 299-7416.  
For Technical Enquires (UK) call + 44 (0) 1628 644354.

### Symbols

	Consult instructions for use
	Temperature limitation
	Do not re-use
	<i>in vitro</i> diagnostic medical device
	Sterilized using radiation
	Caution refer to accompanying document

	Manufactured by
	Batch code
	Use by expressed as CCYY-MM or CCYY-MM-DD
	Serial number
	Catalog number



