

USA Product Label

AlphaTRAK Blood Glucose Control Solution

Product Description:

Glucose control solution allows you to perform quality control tests in order to ensure that the AlphaTRAK Blood Glucose Monitoring System is working properly and that you can rely on the test results. For detailed instructions on how to perform a control solution test, please refer to the 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

A Control solution test should be performed:

- When you first get the meter, before doing a blood test.
- When you begin using a new vial of test strips.
- If you have forgotten to close the test strip vial.
- When you suspect that the meter or test strips are not working properly.
- When the blood glucose test results are not consistent with how the animal is acting, or when you think the results are not accurate.
- If you drop the meter.
- Upon advice of a veterinarian.

In order to perform a control solution test, you need an AlphaTRAK Meter, AlphaTRAK Test Strips, and AlphaTRAK Control Solution. A control solution test follows exactly the same procedures as a test with a drop of blood. Shake the control solution well before each use. Gently touch one edge of the test strip to the control solution. Make sure 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, your meter and test strips are working properly.

If the test result is not within the range printed on the test strip vial:

- Repeat the test to check the result.
- You may not be following the correct test procedure.
- The code set in the meter may not match the test strips 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 control solution may have expired or may have been diluted.
- Control solution test performed outside of 59° F- 104° F.

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 mg/dL to 500 mg/dL.

Accuracy:

The accuracy of the AlphaTRAK Blood Glucose Monitoring System has been demonstrated by comparison of measured blood glucose test results to those obtained from a reference laboratory.

Warning:

Always store the control solution at room temperature. 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 solutions 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.