Blood Ketone Test Strips

For animal use. NOT FOR human use.

PRINCIPLE AND INTENDED USE

The CentriVet™ Blood Ketone Test Strips are thin strips with a chemical reagent system which work with the CentriVet™ GK Blood Glucose & Ketone Monitoring System to accurately read the measurement of β-Ketone in whole blood. The system is tested to accurately read the measurement of β-Ketone in whole blood within the range of 0.0-8.0 mmol/L.

MATERIALS PROVIDED

CentriVet™ Blood Ketone Test Strips

MATERIALS REQUIRED BUT NOT PROVIDED

Ketone Control Solution

COMPOSITION

Each test strip contains the following reactive chemicals:

- 3-Hydroxybutyrate dehydrogenase < 10 IU, Mediator < 100 µg, Buffer, Non-reactive Ingredient.

STORAGE AND HANDLING

- Store test strips in a cool, dry place at room temperature, 5-30°C (41-86°F).
- Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This is to ensure accurate results.
- Do not store the test strips outside their protective packet. Test strips must be stored in the original packet with the cap tightly closed.
- Do not use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or other harsh chemicals that contain bleach.
- Do not transfer the test strips to a new vial or any other container.
- Do not use the test strips if the cap is broken or the vial is open or cracked.
- Do not use the test strips immediately after removing it from the vial.
- Use the test strips immediately after removing it from the vial.
- Do not use test strips past the expiration date printed on the vial.
- Use test strips past the expiration date may produce incorrect test results.

NOTE: All expiration dates are printed in Year-Month format. 2016-01 means January, 2016.

- A new vial of test strips may be used for 6 months after first being opened. When using the opened vial expiration date on the vial label after opening.

PRECATIONS

For animal use.

- Use the test strips that are kept only outside the animal’s body for testing purposes. Do not test with human blood.
- Do not use test strips after the expiration date shown on the vial. Expired test strips may give incorrect blood ketone readings.
- Do not use test strips that are torn, bent, or damaged in any way.
- Do not reuse test strips.
- Only apply the sample to the tip of the test strip.
- Do not apply blood or control solution to the top of the test strip. This may result in an inaccurate reading.
- Check the code number before running a blood Ketone test. Make sure the code number on the top of the test strips you are using matches the code number that appears on the meter display.
- Check that the code letter on the top side of the code chip before running a blood Ketone test. Make sure that the code letter on the top side of the code chip matches the code letter that appears on the box and that it is being used for the correct species of animal you are testing.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This damage can cause incorrect readings.

Keep the test strip vial away from children.

- Consult your veterinary professional before making any changes in your animal’s treatment plan based on your animal’s blood ketone test results.

- Blood ketone ranges have not been established in this insert, consult your animal’s veterinary records for guidance at high levels of Vitamin C and N-acetylcysteine when in blood at normal concentration level does not significantly affect results. N-acetylcysteine in the blood at abnormally high level does not significantly affect results. N-acetylcysteine in the blood at abnormally high levels will cause interference and produce falsely high blood Ketone measurements. Do not use on your animal during or soon after an N-acetylcysteine treatment.

- The system is tested to accurately read the measurement of β-Ketone in whole blood within the range of 0.0-8.0 mmol/L.

- Fatty substances (Triglycerides up to 5000 mg/dl or Cholesterol up to 500 mg/dl) have no major effect on blood ketone test results.

- The CentriVet™ Blood Ketone Test Kit has been tested and shown to give accurate results up to 10,000 ft (3,048 meters).

- Test results may be erroneous if the animal is severely dehydrated, or severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state.

- Dispose of blood samples and materials carefully. Treat all blood samples as infectious and follow all local regulations when disposing of blood samples and materials.

INSTRUCTIONS FOR USE

1. Open the cap of the test strip vial to remove only a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.

2. Run the blood β-Ketone test following the instructions contained in the user’s manual.

3. The blood β-Ketone test result will be shown on the meter display window. This result is the β-Ketone test result. This test result does not establish blood ketone ranges for your animal. Your veterinarian should give you a range that is normal for your animal. If your animal tests outside of this range, contact your veterinarian and report the abnormal test results.

REFERENCE FOR THE RESULTS

- The blood β-Ketone test results are shown on the meter only in millimoles of β-Ketone per liter of blood (mmol/L).

- The meter displays blood β-Ketone test results between 0.0 and 8.0 mmol/L.

- The test strip insert does not establish blood ketone ranges for your animal. Your veterinarian should give you a range that is normal for your animal. If your animal tests outside of this range, contact your veterinarian and report the abnormal test results.

CHECKING THE SYSTEM

The meter must be handled carefully. See the user's manual for detailed instructions for meter care. The ketone quality control test should be used to maintain the meter and the CentriVet™ GK Blood Glucose & Ketone Meter and the CentriVet™ Blood Ketone Test Strips are working together properly. Follow the instructions in the user manual if you are performing a quality control test to control the system range. The control range solution will be used on the test strip vial label under the code number. If you think this test strip may not be working, contact the meter distributor for help.

For correct use of test strips, control solution tests should fall within the CTRL range.

CAUTION: If the quality control test result falls outside the control range shown on the test strip, DO NOT use the system to test your animal’s blood, as the system may not be working properly. If you cannot correct the problem, contact your distributor for help.

LIMITATIONS

- The CentriVet™ GK Blood Glucose & Ketone Meter, CentriVet™ Blood Ketone Test Strips and other CentriVet™ components have been designed, tested and proven to work together to effectively provide accurate blood ketone measurements in a variety of species of animals. Do not use components from other brands.

- Do not use the meter in any manner not specified by the manufacturer. Otherwise, the protection provided by the meter may be impaired.

- Do not use test strips for any use not for human use.

- The CentriVet™ Ketone Test Strips are for testing fresh capillary or venous whole blood. Do not use with dialyzed, neonatal serum or plasma samples.

- The CentriVet™ GK Blood Glucose & Ketone Monitoring System is indicated for veterinary professional use and over the counter sales. The counter purchasers should be using the CentriVet™ GK Blood Glucose & Ketone Monitoring System under the guidance of a veterinary professional.

- Blood β-Ketone measurement with venous blood must be performed within 15 minutes of sample collection.

- Anticoagulants such as heparin, EDTA or sodium citrate, are recommended for best results in using venous blood. Use of anticoagulants such as indocyanine or those containing fluoride is not advised.

- Very high (above 60%) and very low (below 20%) hematocrit can cause false results. Talk to your veterinary professional to find out your animal’s hematocrit.

- Vitamin C (ascorbic acid) when occurring in blood at normal concentration level does not significantly affect results. N-acetylcysteine in the blood at abnormally high levels will cause interference and produce falsely high blood β-Ketone measurements. Do not use on your animal during or soon after an N-acetylcysteine treatment.

Linear Regression Results: CentriVet™ Blood Ketone Test Strips vs. Random D-3-Hydroxybutyrate (Randt) assay kit as Reference. The results with three lots are shown in the charts below.

Linear Regression Results: CentriVet™ Blood Ketone Test Strips vs. Random D-3-Hydroxybutyrate (Randt) assay kit as Reference.

Blood Sample Slope Intercept R N

<table>
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<th>Blood Sample</th>
<th>Slope</th>
<th>Intercept</th>
<th>R</th>
<th>N</th>
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System Accuracy Results for D-3-Hydroxybutyrate Concentration

- Within ±10%: 0-1.5 mmol/L
- Within ±15%: 1.5 mmol/L - 8.0 mmol/L
- Within ±20%: > 8.0 mmol/L

System Accuracy Results for D-3-Hydroxybutyrate Concentration

- Within ±10%: 0-1.5 mmol/L
- Within ±15%: 1.5 mmol/L - 8.0 mmol/L
- Within ±20%: > 8.0 mmol/L

For complete instructions, please refer to the CentriVet™ GK Blood Glucose & Ketone Monitoring System user’s manual. For additional questions or issues with this product, please contact your dealer for help.

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