CERA-PET Blood Glucose Test Strip

IVD

Read this entire insert thoroughly before you start using the CERA-PET™ Blood Glucose Test Strip. Only use CERA-PET™ Blood Glucose Test Strips with CERA-PET™ Blood Glucose Test Meter. Please follow a veterinarian/veterinary sugeon's direction on frequency of testing and time of day for testing. Keep this insert for future reference. If you have any inquiries, please contact your local distributor.

Intended Use

The CERA-PET™ Blood Glucose Monitoring System is intended for use in veterinary and medical professional setting to monitor blood glucose level in dogs and cats. It is also intended for use in the home setting to monitor blood glucose levels in dogs and cats.
The CERA-PET™ Blood Glucose Monitoring System is intended for *in vitro* diagnostic use.

Principle of Measurement

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the test strip.
The test meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

CAUTION

The CERA-PET™ Blood Glucose Test Strip 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 CERA-PET™ blood glucose test results, without the consent and advice of a veterinarian/veterinary surgeon, is not recommended.

Reagent Composition

- Each CERA-PET™ Blood Glucose Test Strip contains:
  - Glucose dehydrogenase(Microorganism) ..... 4 units
  - Potassium ferricyanide ..... 0.05 mg
- Each vial cap contains a desiccant.

Calibration

When using the CERA-PET™ Blood Glucose Monitoring System for the first time, or before using a new box of test strips, you will need to calibrate the test meter. There are two code keys (Dog and Cat) in every box of test strips. Calibration can be easily done by inserting the code key into the test meter. Only use the code key that is packaged with the box of test strips that you are using.

- Press the ON/OFF button to turn the test meter on.
- Insert the code key completely into the code key port with the code number facing up and the code number will appear on the LCD display. Make sure that the code numbers on the display, on the code key, and on the test strip vial are the same.
- Remove the code key. The test meter is now ready for blood glucose test. Store the code key with test strip box. Do not discard the code key until you have used all of the test strips in the box.

- **Glucose Control Solution Test**

  Checking the System with the CERA-PET™ Blood Glucose Control Solution contains glucose that reacts to the test strips. By comparing the result tested using the control with the expected range printed on the test strip vial label, it is able to check that the test meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

  1) Insert the test strip into the insert port of the test meter.
     The blood symbol will start blinking.
  2) Prepare the Glucose Control Solution.
     Shake the Glucose Control Solution vial thoroughly.
  3) Apply glucose control solution.
     Aim directly at the absorbent hole of the test strip. Squeeze the vial again to get another drop and the drop will be automatically drawn in the test strip. Make sure the confirmation window is completely filled.
  4) The test meter will count down from 5 seconds and then display the Glucose Control Solution test result.

  Perform a Glucose Control Solution Test if
  - You would like to test your system without using a blood sample.
  - You are using the test meter for the first time.
  - You suspect the test meter or test strips may not be functioning properly.
  - Test results appear to be abnormally high, or low or are not consistent with the symptoms you are experiencing.
  - The test strip vial was left open.
  - You are using a new vial of test strips.
  - You dropped the test meter.

NOTE

The results obtained from Glucose Control Solution test do not indicate your pet glucose level.
※ The CERA-PET™ Blood Glucose Control Solution is sold separately. If you want to buy, please contact your local distributor.

CAUTION

Use the CERA-PET™ Blood Glucose Test Meter only with the CERA-PET™ Blood Glucose Test Strip. Glucose Control Solution is sold separately. Do not use the control solution after expiration date as printed on the vial. Use the control solution within 4 months after opened. It is recommended to record the discard date on the coming 4 months on the Glucose Control Solution vial as a reminder when to dispose the opened control solution.

Testing Blood Glucose

- Getting a blood drop
  - Use Lancing Device to obtain a blood sample from dog and cat.
  - Consult a veterinarian/veterinary surgeon for a recommended sampling method and instruction.

  1) Select the test site.
     - There are many sites to obtain capillary blood samples.
       - The marginal ear vein in both cats and dogs
       - Paw pad in cats and dogs
       - Inner or outer lip, dog only
       - Leg callus, usually dogs
     - Warming the area will help increse blood flow.
       - Gently rubbing the test site
       - Applying a warm(not hot) cloth to the test site. (If using a wet cloth, place the cloth inside a plastic bag to avoid diluting the blood sample.)
  2) Wash your hands with warm water and soap to ensure accurate results. Thouroughly dry your hands.
  3) After select the test site, remove hair and debris. And disinfect with alcohol swab.
  4) Use the lancing device to obtain a blood drop.
  5) To get a drop of blood from the test site, Press the release button. You will hear a click, indicating that the puncture is complete.
  6) Gently squeeze the punctured area to obtain blood sample.
     - Gently apply pressure to the test site with sterile gauze or cotton wool to help stip the blood flow.
  7) Gently squeeze the punctured area to obtain blood sample.
  8) Remove the lancet.
     After pulling the sliding barrel out. Push the ejection system upwards to remove the lancet.
  9) Place the protective cap on a hard surface and push the exposed tip into the protective cap.

WARNING

A lancet should only be used once. Please dispose the used lancet in a safe manner in order not to cause accidental injury and infection. Never share a lancet of the lancing device with another animal or person. Always use a new lancet.

- **Performing a Blood Glucose Test**

  1) Insert test strip
     Remove the test strip from the vial and immediately close the cap.
     Insert the test strip into the insert port.
     The 'blood' symbol '🩸' will blink on the display.
  2) The code key must match the code number on the test strip vial and LCD display. Please check the right direction to insert the code key into the test meter

NOTE

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

Species	Code Number
Dog	See code identified on the vial
Cat	See code identified on the vial

3) Obtain a blood sample
For dogs and cats, refer to the CERA-PET™ Blood Glucose Monitoring System User Guide or veterinarian/veterinary surgeon for blood sampling.

4) Apply blood to the test strip
When the 'blood' symbol is flashing on the display, apply a drop of blood to the absorbent hole until blood has completely filled the confirmation window.
- The test meter will automatically shut down after 2minutes of inactivity. The test meter will countdown for 5 seconds and then display a result. The reading is automatically stored in the test meter memory.

5) Remove and discard the test strip from the test meter.
For dogs ad cats, refer to the CERA-PET™ Blood Glucose Monitoring System User Guide or veterinarian/veterinary surgeon for blood sampling.

Test Result

The CERA-PET™ Blood Glucose Test Meter will display results between 10~900 mg/dL (0.6~50.0 mmol/L).

• **Normal Blood Glucose Results :**

Normal Blood Glucose Level[1)]
72 ~ 140 mg/dL (Dog, Cat)

• **Low Blood Glucose Results :**
If the test results are less than 10 mg/dL (0.6 mmol/L),"Lo" will appear on the display indicating hypoglycemia (low blood glucose). For dog and cat use at home, treat low blood glucose immediately as recommended by a veterinarian/veterinary surgeon.

• **High Blood Glucose Results :**
If the test result is above 900 mg/dL (50.0 mmol/L), "HI" will appear on the display. This indicates severe high blood glucose (hyperglycemia). For dog and cat use at home, treat high blood glucose immediately as recommended by a veterinarian/beterinary surgeon.

※ Low or high blood glucose readings can indicates a potentilally serious medical condition. If the blood glucose level is unusually low or high, or if the animal dose 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 results is less than 65 mg/dL (3.6 mmol/L) and highter thatn 250 mg/dL (13.9 mmol/L) for dogs and cats.

Limitations

• **Hematocrit Effect:**
Hematocrit below 10% and hematocrit above 70% may cause inaccurate result. Please consult your healthcare professional if you do not know your hematocrit level. Use only fresh whole blood. Do not use serum or plasma.

• **Metabolites:**
Ascorbic acid at normal blood concentration does not significantly affects glucose readings. High concentrations of acetaminophen, dopamine, L-dopa, methyldopa and uric acid may cause inaccurate test results. Blood glucose readings should be interpreted with caution.

• **Altitude:**
Test strips may be used at altitudes up to 13,200 feet (4,000m) without an effect on test results.

• **Operation Temperature:**
High or low in-operation temperature can affect test results. The high or low temperature, above 40℃ (104 ℉) or below 4℃ (39℉), may cause inaccurate results.

Storage and Handling

- Store the test strips at a temperature between 1℃~32℃ (34℉~90℉). Improper storage may cause the test strips to give false readings.
- Keep the test strips away from direct sunlight.
- Do not store the test strips in areas of high humidity.
- Do not store the test strips near bleach as well as bleach containing products.
- Do not use the test strips after expiration date. Results will be inaccurate.
- Test strips expire 4 months after first opening. Write the expiry date on the test strip vial upon first opening.
- Do not handle the test strips with wet or dirty hands.
- After removing the CERA-PET™ Blood Glucose Test Strip from the vial, close the vial cap tightly.
- Use each test strip immediately after removing it from the vial.
- Store the test strips in their original vial only. Do not transfer them to a new vial or other container.
- Do not bend, cut, or alter a test strip.
- Test strips are single use only. Do not reuse.
- Keep away from children. If this product is mishandled, it may cause serious harm or injury.

CAUTION

- If you have symptoms which are not consistent with your pet blood test results and you have eliminated common procedural errors described in the user manual, contact Veterinarian/veterinary surgeon immediately.
- Any change in medication, based on the CERA-PET™ blood glucose test results, without the consent and advice of a veterinarian/veterinary surgeon, in not recommended.

Performance Characteristics

The performance of the CERA-PET™ Blood Glucose Test Strips has been tested both in laboratory and clinical studies. The testing range of the CERA-PET™ Blood Glucose Monitoring System is 10 to 900 mg/dL depending on the version of the meter.

• Precision

1) Within-run Precision
The within-run precision testing was assessed in a laboratory study that used pooled venous blood sample. Each of the samples was measured 10 times per each for precision.

Level	No.of assay	Mean(mg/dL)		SD(mg/dL)		C.V(%)	
		Dog	Cat	Dog	Cat	Dog	Cat
1	100	52.3	53.1	2.7	2.9	5.2	5.5
2	100	98.2	96.4	3.5	3.7	3.6	3.8
3	100	129.5	125.4	4.6	4.3	3.6	3.4
4	100	210.2	212.5	6.7	7.0	3.2	3.3
5	100	345.5	343.9	8.9	8.5	2.6	2.5

2) Day to day Precision
The day to day precision testing conducted with 2 levels of glucose prepared from control solutions. Each sample was measured 10 times a daily for 20 days using ten meters across multiple lots.

Level	No.of assay	Mean(mg/dL)		SD(mg/dL)		C.V(%)	
		Dog	Cat	Dog	Cat	Dog	Cat
Normal	200	120.5	120.8	3.7	3.9	3.1	3.2
High	200	319.4	320.4	8.2	8.0	2.6	2.5

• Accuracy

Species	No. Sample Tested	Reference Analyzer	Reference Range of Samples Tested(mg/dL)	Correlation with Reference Analyzer(R^2)
Dog	50	YSI 2300 Plus	69 ~ 304	0.9851
Cat	50	YSI 2300 Plus	49.8 ~ 250	0.9869

Symbol Information

IVD	*In vitro* diagnostic medical device
	Do not re-use
	Consult instructions for use
	Temperature limitation
	Use by
SN	Serial number
LOT	Batch code
REF	Catalog number
	Manufacturer

1) Home Monitoring of Blood Glucose Concentration in the Management of Diabetes MellitusHome, Compendium small anima Vol.23. No.6 June 2001: p544~575

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

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