

OnTarget Ketone Test Strip BK333P

User Instructions



The PetTest OnTarget control solution is for use with the PetTest OnTarget Blood Glucose & β -Ketone Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Test Principle

The system measures the amount of β -ketone in whole blood. The β -ketone testing is based on the measurement of electrical current generated by the reaction of β -ketone with the reagent of the strip. The meter measures the current and calculates to the β -ketone level, which is showed on the display. The strength of the current produced by the reaction depends on the amount of β -ketone in the blood sample. See page 20 of the PetTest OnTarget User Manual for how to test.

Chemical Components

β -Hydroxybutyrate Dehydrogenas	5.3%
Mediator	4.2%
Non-reactive ingredients	90.5%

Warning and Precautions

- The PetTest OnTarget Blood Glucose & β -Ketone Monitoring System is intended for use on pets (dogs and cats). DO NOT use on humans!
- The test strips are for single use only. DO NOT reuse test strips.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after having performed cleaning and disinfection. Details of the cleaning and disinfecting procedure could be found in the section Cleaning and Disinfection in the owner's manual.
- Due to the risk of blood-borne pathogen transmission, you should wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- For in vitro diagnostic use only.
- Excessive dehydration may cause low results. If you believe your pet is dehydrated, consult your veterinarian immediately.
- Inaccurate results may occur if your pets are severely hypotensive individuals or in shock.
- Inaccurate results may occur if your pets are in a hyperglycemic-hyperosmolar state. Critically ill pets should not be tested with β -ketone meters.
- As a quality control check to verify the accuracy of your β -Ketone test results, use PetTest Control Solution as instructed on page 14 of the PetTest OnTarget Meter User Manual.

Storage and Handling

- Store the test strips at temperatures between 39.2°F and 89.6°F (4°C and 32°C). Do not freeze.
- **Any test strip removed from the foil wrap must be used immediately! Test strips removed from foil wrap cannot be stored for later use.**
- Do not use the test strips after the expiration date printed on each foil.
- Perform tests at temperature between 50°F and 104°F (10°C and 40°C) and between 15%-85% humidity.
- Keep the test strips away from direct sunlight. Do not store the test strips in areas of high humidity.
- Only touch the test strips when your hands are dry. As a precaution, only touch the foil. Test strip must be used immediately after opening foil wrap
- Do not bend, cut or alter the test strips in any way.

Before You Begin

- Please read both this information and the OnTarget Blood Glucose Monitoring System User's Manual before using OnTarget β -Ketone test strips to perform Ketone testing on your pet.
- Failure to follow instructions may cause incorrect test results.
- This device is for use under the direction of a veterinary professional.
- Home testing results are not a substitute for veterinary advice.
- The OnTarget Blood Glucose Monitoring System is designed to aid in the treatment of Pet Diabetes. Always consult with your pet's veterinarian prior to starting new treatments. PetTest makes no recommendations on treatment options and is solely a system for measuring blood glucose and β -Ketone levels in dogs and cats.

Intended Use

PetTest OnTarget Blood Glucose & β -Ketone Monitoring system is intended for use outside of the body (in vitro diagnostic use). It is used for quantifying blood glucose and β -ketone (beta-hydroxybutyrate) level of dogs and cats in capillary whole blood. It should not be used for the diagnosis of diabetes or ketoacidosis. It also can not be used for the testing of neonatal or arterial blood.

The PetTest OnTarget Blood Glucose & β -Ketone Monitoring system consists of the PetTest OnTarget Blood Glucose & β -Ketone Meter, the Blood Glucose Test Strips and the β -Ketone test strips. The PetTest OnTarget Blood Glucose & β -Ketone Meter is used with Blood Glucose test strips and β -ketone (beta-hydroxybutyrate) test strips.

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Before Testing

Calibration: You must calibrate the meter every time you begin to use a new box of β -Ketone test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the box.

How to Code Your Meter (for β -Ketone)

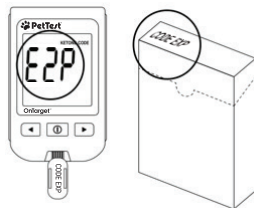
1. Insert the code strip when the monitor is off. Wait until the code number appears on the display. **NOTICE: Make sure the code number on display and box are the same.**
2. Remove the code strip, the display will show "OFF". This tells you that the meter has finished coding and is ready for β -ketone testing.

Checking the Code Number

You need to make sure that the code number displayed on the meter matches the number on your box before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and repeat the calibration procedure. If the problem persists, contact Customer Service for help. **NOTICE: The codes used in this manual are examples only; your meter may display a different code.**

Warning

- It is important to make sure that the LCD displayed code is the same as the code on your box before testing. Failure to do so will get inaccurate results.
- The code number for β -Ketone strip is 3 characters; please ensure you are using the correct strips for the test.
- If the LCD displayed code is not the same as the code on your box and the code number cannot be updated, please contact Customer Service for assistance.



Testing Procedure

1. Completely clean the testing site of your pet. If you use an alcohol swab, make sure that it is completely dry before lancing.
2. Insert a test strip into the meter. The meter will turn on automatically.
3. Press the Right Arrow button to select the appropriate test mode (dog/cat/control solution) as desired.
4. Use a lancing device or safety lancet to obtain a blood sample. The minimum blood sample size is $0.3\mu\text{L}$. When the flashing blood drop symbol appears on the display, apply blood to the tip of the test strip until blood has completely filled the confirmation window. **Hold the meter and test strip at a 45° angle to your pet to most effectively collect the blood.** Please note that if the confirmation window is not completely filled with blood, the test result may be inaccurate.
5. The meter starts counting down, and your test result is then displayed on screen. The result is automatically stored in the meter's memory.
6. Turn the meter off by removing the strip. Properly discard the used strip in a sharps container.

As a precaution, wash hands thoroughly with soap and water after the testing procedure. For detailed information on Cleaning and Disinfection, please refer to the PetTest OnTarget Blood Glucose & β -Ketone Monitoring System User's Manual.

The used lancet and the used test strip may be potentially biohazardous. **Please discard all medical waste responsibly following your local or state medical waste regulations.**

How to Read Your β -Ketone Test Result

- The test provides a quantitative measurement of β -ketone is from 0.0 to 8.0 mmol/L.
- If your test result is greater than 8.0 mmol/L, the "HI" message will appear on the meter display. This indicates a very high β -ketone level. Repeat the test with a new test strip; if you experience similar results immediately contact your veterinarian for help.
- This test strip insert does not establish blood ketone ranges for your pets. Your veterinarian should give you a range that is normal for your pets. If your pets test outside of this range, contact your veterinarian for help.

Expected Blood Glucose Values

The normal value for blood glucose in healthy dogs and cats is 75–120 mg/dL (4.2–6.7mmol/L).¹ Many factors will affect blood glucose level, such as food intake, medication dosages, health, stress, or exercise. The expected blood glucose level appropriate for your pet should be determined by your pet's veterinarian.

Questionable or Inconsistent Results

- Be sure the sample drop of blood completely fills the confirmation window of the β -ketone test strip.
- Confirm that test strips are within the expiration date.
- Check meter and strip performance by using PetTest OnTarget control solution.
- **High β -Ketone test results may cause a serious medical condition. If your pets continue to get unusually high results, consult your veterinarian.**

Quality Control Using Control Solution

PetTest Level 3 Control Solution is used to check that your meter and the test strips are working together as a system. It is very important that you do this simple check routinely to make sure you get correct results. Control range can vary for each foil wrapped box of test strips. Always refer to the control range printed on the foil of your current box.

When to check your system with control solution:

- Before using the meter for the first time.
- When you begin using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- After cleaning and disinfection of the meter.
- At least once a week.
- To check your technique.
- When blood glucose test results are not consistent with how your pet is acting, or if you think results are inaccurate.
- When your test strips are exposed to extreme environmental conditions (below 39°F (4°C), or above 104°F (40°C), or humidity levels below 15%, or above 85%).
- If you drop the meter.

If the control solution test result falls outside the specified range, repeat the test. Results falling outside the range may be caused by:

- Performing the test improperly.

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- Not shaking the control solution vial well enough.
- Using expired or contaminated control solution and test strips.
- Control solution is stored outside of the specified temperature range, which is from 35°F to 86°F [2°C to 30°C].
- Not discarding the first drop of control solution.
- Using a damaged meter.

If you continue to get control solution test results that fall outside the range, the test strip and the meter may be not working properly. DO NOT use the system to test the blood glucose of your pet. Contact Technical Support for help. Toll-free: 1-866-373-2824

Limitations

- **Blood Source:** Use only Capillary and Venous whole blood. Do not use serum or plasma.
- **Hematocrit Effect:** When hematocrit is between 30% and 60%, the β -ketone result is not affected. If you do not know your hematocrit level, consult your health care provider.
- **Neonatal Use:** The test strips shall not be used for the testing of newborn animals.

Performance Characteristics

Accuracy: The performance of β -Ketone test strips has been tested both in laboratory (ADVIA Chemistry XPT) and clinical studies. The testing range of the PetTest OnTarget Blood Glucose & β -Ketone Monitoring System is from 0.0 to 8.0 mmol/L.

Linear Regression Results:

PetTest OnTarget Blood β -Ketone Meter vs. ADVIA Chemistry XPT Reference

Sample Blood	Slope	Intercept	RSQ
Canine whole blood	0.9699	0.0174	0.9975
Feline whole blood	0.9527	0.0805	0.9979

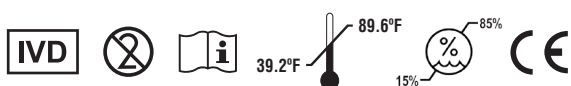
System Accuracy Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L

Blood Sample	Within \pm 15%	Within \pm 20%
Canine whole blood	93.3%	98.3%
Feline whole blood	91.7%	98.3%

System Accuracy Results for D-3-Hydroxybutyrate Concentration < 1.5 mmol/L

Blood Sample	Within \pm 0.2mmol	Within \pm 0.3mmol
Canine whole blood	95.8%	100%
Feline whole blood	91.7%	95.8%


System Accuracy for Results for D-3-Hydroxybutyrate Concentration ≥ 1.5 mmol/L and < 1.5 mmol/L



Symbol Information

-  In vitro diagnostic use
-  Do not reuse
-  Use by/Expiry date
-  Store at
-  See instruction for use
-  Caution, consult accompanying documents
-  Keep away from sunlight
-  Humidity
-  Biological risks
-  Lot number
-  Manufacture date
-  Serial number
-  CE marking

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 Toll-free: 1-866-373-2824
 (7 days a week, 24hrs a day)
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