bkt Best Ketone Test

ver 2.0 2019-06
312-4279400-002

Blood Glucose Test Strip

Warnings

- For in vitro diagnostic use (for use outside of the body only).
- For single use only.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Please read this sheet and your TD-4279 β-ketone & Blood Glucose Monitoring System Owner's Manual before you use this test strip. Use only Best Ketone Test Test Strips with TD-4279 β-ketone & Blood Glucose Monitoring System to obtain accurate results, and to be covered by the manufacturer's warranty.
- Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- This system is not for use in patients in hyperglycemic-hyperosmolar state, with or without ketosis.
- This system should not be used on critically ill patients.
- This system should not be used on patients with impaired peripheral circulation, severe dehydration as a result of diabetic ketoacidosis or severe hyperglycemia, hyperosmolar non-ketotic coma or shock.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.
- For over the counter use.

Intended Use

The Best Ketone Test Blood Glucose Test Strip, when used together with the TD-4279 β-Ketone & Blood Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood from the finger. This system is intended for single-patient use (lay-users at home) and should not be shared. It should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

Limitations

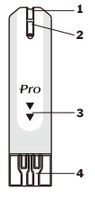
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- Hematocrit: The hematocrit level is limited to between 0% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- Acetaminophen in your blood >6.25 mg/dL might affect the reliability of your blood glucose results. If you are taking Tylenol, your glucose results may not be reliable. If you are unsure, then ask your doctor.
- If you have a disease or condition that elevates your blood uric acid level (>10 mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your doctor.
- Reduced glutathione level to > 30 mg/dL may affect the glucose results. If you are unsure, then ask your doctor.
- Pralidoxime iodide level to >5 mg/dL may affect the glucose results. If you are unsure, then ask your doctor.
- Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.

Storage and Handling

IMPORTANT: Do not use the test strips if they have expired.

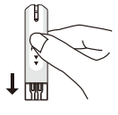
- Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it.
- Store the test strips in a cool, dry place between 35.6°F and 86.0°F (2°C and 30°C) and 10% to 85% relative humidity.
- Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers.
- Do not touch the test strips with wet hands.
- Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.
- Keep the vial closed at all times.
- Do not bend, cut, or alter the test strip.

Strip Appearance



1. Absorbent Hole
Apply a drop of blood here. The blood will automatically be absorbed.
2. Confirmation Window
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.
3. Test Strip Handle
Hold this part to insert the test strip into the slot.
4. Contact Bars
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

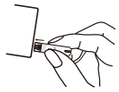
ATTENTION



The front side of the test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

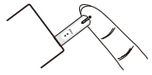
Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.



STEP 1

Insert the test strip fully into the slot of the meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks. Please ensure you are using the Best Keto Test blood glucose strip for performing the test.



STEP 2

Obtain 1.0 µL blood sample and apply it to the test strip. An insufficient quantity of blood will provide inaccurate results. Touch the blood drop to the absorbent hole of the test strip, and wait until the confirmation window is fully covered. DO NOT apply a smeared blood sample. The meter will start counting down.

STEP 3

After 5 seconds, the meter will display your blood glucose test result. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.

Please refer to your Owner's Manual for more information.

Cleaning and disinfection of your meter are required to reduce the risk of bloodborne pathogen transmission.

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt, blood, or any other body fluid with the wipe. Use a second wipe to disinfect the meter by following the disinfecting procedure. Please refer to your Owner's Manual for more information about the cleaning and disinfection procedures with a disinfecting wipe.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed either in millimoles of glucose per liter of blood (mmol/L) or in milligrams of glucose per deciliter of blood (mg/dL). The measurement range of this meter is 10 to 700 mg/dL (0.5 to 38.9 mmol/L).

Reference values

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meal	**< 100 mg/dL (5.6 mmol/L)**
2 hours after meal	**< 140 mg/dL (7.8 mmol/L)**

American Diabetes Association. Standards of Medical Care in Diabetes- 2018 Jan; 41(Supplement 1): S1-S2.

Please consult your doctor to determine a target range that works best for you.

Questionable or inconsistent results

If your test results are unusual or inconsistent with how you are feeling:
- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiration date of the test strips.
- Check the performance of your meter and test strip with the control solutions.

PLEASE NOTE: Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our control solutions contain a known amount of glucose that can react with test strips.

Do a control solution test in following conditions:
- First time you use the meter
- At least once a week to routinely check the meter and test strips
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process
- You have dropped or think you may have damaged the meter

You can check the performance of meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial. Checking regularly can ensure your test results are accurate. If the quality control check fails, conduct the quality control check again or contact customer service if the quality control check continues to fail. Please refer to the Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of the control solutions may vary with each new vial or package of test strips. Make sure you check the range on the label of your current vial or on the current package.

Chemical Components

> Glucose dehydrogenase (E. coli)	8 %
> Electron shuttle	55%
> Enzyme protector	8 %
> Non-reactive ingredients	29%

Performance Characteristics

Sample Size: 1.0 µL
Reaction Time: 5 seconds
System Measurement Range: 10 to 700 mg/dL (0.6 to 38.9 mmol/L)

Accuracy

The TD-4279 meter was tested in the hand of 160 lay users using capillary blood samples, covering the range between 51–525 mg/dL. The results are compared to the laboratory method and are shown below:

Table 1. Results for glucose concentration <75 mg/dL

Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL
22/33(66.7%)	32/33(97.0%)	33/33 (100%)

Table 2. Results for glucose concentration ≥75 mg/dL

Within 5%	Within 10 %	Within 15 %	Within 20 %
100/127 (78.8%)	122/127 (96.1%)	125/127 (98.4%)	127/127 (100%)

Note: When Best Keto Test results are compared to the laboratory results, difference values below 75 mg/dL are expressed in mg/dL, while those above 75 mg/dL are compared as a percentage.

Precision

Precision studies using control solutions (intermediate precision) and blood samples (repeatability) are shown below:

Table 3. Intermediate precision

Control solutions	Y1	B2	W3
Mean (mg/dL)	48.5	131.7	331.4
SD (mg/dL)	2.15	4.67	11.24
CV (%)	4.44%	3.54%	3.39%

Table 4. Repeatability

Blood samples	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	47.3	92.2	132.3	224.5	387.4
SD (mg/dL)	2.03	2.80	4.33	6.70	11.73
CV (%)	4.30%	3.03%	3.27%	2.98%	3.03%

Manufactured for:
Best Ketone Test
2086 East Canal Dr.
PMB 128
Turlock, CA 95380 USA
Please contact your healthcare provider for immediate help.

bestketonetest.com

Use Only with TD-4279 β-Ketone & Blood Glucose Monitoring System.

Read instructions before use.
Store at 35.6°F to 86.5°F, and 10% to 85% R.H. For in vitro diagnostic use.
For single use only.
For self-testing.