

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 test strips. Use only Best Ketone Test β-Ketone Test Strips with TD-4279 β-Ketone & Blood Glucose Monitoring System to obtain accurate results, and to be covered by the manufacturer's warranty.
- ☒ This system is not for use in patients with abnormally low blood pressure, or those who are in shock, as well as in hyperglycemic-hyperosmolar state, with or without ketosis.
- ☒ This system should not be used on critically ill patients, or 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

Best Ketone Test β-Ketone Test Strip, when used together with the TD-4279 β-Ketone & Blood Glucose Monitoring System, allows your β-Ketone levels to be measured by yourself at home. It uses fresh whole blood samples 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.

About Alternative Site Testing (AST)

IMPORTANT: There are limitations for performing AST. Please read the β-ketone & blood glucose monitoring system Owner's Manual and consult your doctor before you perform AST.

Alternative site testing (AST) is when individuals check their β-Ketone levels using areas of the body other than the fingertip. The β-ketone & blood glucose monitoring system allows AST to be performed on a site other than the fingertip - namely the palm.

- Do NOT use AST if:
- ☒ You think your β-Ketone is low.
 - ☒ Your AST results are inconsistent with the way you feel.
 - ☒ Your routine β-Ketone results often fluctuate.

To obtain a blood sample from the alternative site, please rub the puncture site for approximately 20 seconds before following the procedures of "Testing Your β-Ketone".

Limitations

- ☒ Hematocrit: The hematocrit level is limited to between 10% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- ☒ Neonatal Use: This test strip must not be used for the testing of newborns.
- ☒ 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 open it.
- ☒ Store the test strips in a cool, dry place between 35.6°F and 86°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.
- ☒ Do not touch the test strips with wet hands.
- ☒ Use each test strip immediately after taking it out of the vial or individual foil packet. 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 be automatically absorbed.

2. Confirmation Window
This is where you confirm if enough blood has been applied to the absorbent hole in 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 your 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 may be wrong if the contact bar is not fully inserted into the test slot.

Code Chip Instructions

Calibration

Calibrate the meter each time you begin to use a new vial of ketone test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the meter does not match the number printed on our test strip vial label.

Operation

You must insert the code chip to code the meter and renew the strip's expiry date whenever you begin to use a new box of test strips.

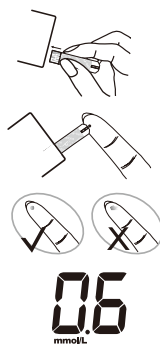
1. Insert the code chip when the monitor is off. Wait until the number and "KETONE" appears on the display.
2. Remove the code chip. The display will show "OFF", and then meter will switch off. This means that the meter has been updated to the new expiry date and is ready for measurement.

Checking the Code Number

You need to make sure that the number displayed on the meter matches the number on your test strip vial before you proceed. If it matches, you can proceed with your test. If the numbers do not match, please stop testing and insert the correct code chip. If the problem persists, contact Customer Support for help.

Testing Your β-Ketone

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.



STEP 1

Insert the test strip fully into the slot of your meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks. Please ensure that you are using the Best Ketone Test Blood Ketone test 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 10 seconds, the meter will display your β-Ketone level. The last reading will be automatically saved in the meter. Turn it off by removal and disposal of the used test strip.

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

Cleaning and disinfection of your meter are required to reduce the risk of blood borne 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

The β-Ketone readings deliver plasma equivalent results and are displayed in millimoles of ketone per liter of blood (mmol/L).

The β-Ketone test measures Beta-Hydroxybutyrate (β -OHB), the most important of the three β-Ketone bodies in the blood. Normally, levels of β -OHB are expected to be less than 0.6 mmol/L. β -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β-Ketone result is "Lo", repeat the β-Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication program. If your β-Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your β-Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for assistance. You may be at risk of developing diabetic ketoacidosis (DKA)1-6.

References

1. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism 1982;4:1-27.
2. Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997;20:1347-52.
3. Harano Y, Kosugi K, Hyosu T, Suzuki M, Hidaka H, Kashiwagi A, Uno S, Shigeta Y. Ketone bodies as markers for Type 1 (insulin-dependent) diabetes and their value in the monitoring of diabetes control. Diabetologia 1984;26:343-8.
4. Ubukata E. Diurnal variation of blood β-Ketone bodies in insulin-dependent diabetes mellitus and noninsulindependent diabetes mellitus patients: The relationship to serum C-peptide immunoreactivity and free insulin. Ann Nutr Metab 1990;34:333-42.
5. Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. Diabetes 1988;37:1470-77.
6. Hale PJ, Crase J, Natrass M. Metabolic effects of bicarbonate in the treatment of diabetic ketoacidosis. Br Med J 1984;289:1035-8.

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 your test strip is completely filled with blood.
- ☒ Check the expiry date of your test strips.
- ☒ Check the performance of your meter and test strip with the control solution.

PLEASE NOTE: Unusually high or low β-Ketone 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 β-Ketone that can react with test strips. Do a control solution test in the following conditions:

- ☒ First time you use your 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
- ☒ Practicing the testing process
- ☒ You have dropped or think you may have damaged the meter

You can check the performance of the meter, test strips 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 Support 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 solution 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. If the LCD displayed code is not the same as the code on your test strip vial or package, and the code number cannot be updated, please contact Customer Support for assistance.

Chemical Components

- > β-Hydroxybutyrate Dehydrogenase (Pseudomonas sp.) ≥0.5 U 35%
- > Electron shuttle 35%
- > Enzyme protector 10%
- > Non-reactive ingredients 42%

Performance Characteristics

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary and venous whole blood.

Sample Size: 1.0 μL

Reaction Time: 10 seconds

System Measurement Range: 0.1 mmol/L ~ 8 mmol/L

Hematocrit Range: 10% to 70%

Accuracy

The Keto-Mojo β-ketone & blood glucose monitoring system was tested in the hand of 120 lay users using capillary blood samples, covering the rage between 0.04 – 6.77 mmol/L. The results are compared to the laboratory method and are shown below:

Table 1. Results for β-Ketone concentration <2 mmol/L

Within 0.3 mmol/L	Within 0.5 mmol/L
80/89(89.9%)	89/89(100%)

Table 2. Results for β-Ketone concentration ≥ 2 mmol/L

Within 5%	Within 10 %	Within 15 %	Within 20 %	Within 25 %
15/31 (48.4%)	25/31 (80.6%)	30/31 (96.8%)	30/31 (96.8%)	31/31 (100%)

Note: When results of the TD-4279 are compared to the laboratory results, difference values below 2 mmol/L are expressed in mmol/L, while those above 2 mmol/L are compared as a percentage.

Precision

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

Table 3. Intermediate precision

Control solutions	L1	L2
Mean (mmol/L)	0.584	2.592
SD (mmol/L)	0.058	0.072
CV (%)	9.86%	2.78%

Table 4. Repeatability

Blood samples	Level 1	Level 2	Level 3
Mean (mmol/L)	0.513	2.920	4.997
SD (mmol/L)	0.063	0.103	0.177
CV (%)	12.28%	3.53%	3.54%

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.