

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 keto-mojo β-ketone & Blood Glucose Monitoring System Owner's Manual before you use this test strip. Use only TD-4279 Test Strips with TD-4279 Keto-mojo β-ketone & Blood Glucose Monitoring System to obtain accurate results, and 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.

Intended Use

KETO-MOJO TD-4279 Test Strip, when use together with keto-mojo 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

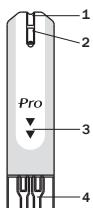
- ▶ Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- ▶ Hematocrit: The hematocrit level is limited to between 0% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- ▶ Acetaminophen 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.

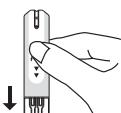
- ▶ Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it. (For strip vial only)
- ▶ Store the test strips in a cool, dry place between 35.6°F and 86.0°F (2°C and 30°C) and 10% to 85% relative humidity.
- ▶ Keep the test strips away 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. (For strip vial only)
- ▶ 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. (For strip vial only)
- ▶ Keep the vial closed at all times. (For strip vial only)
- ▶ 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 with HCT/Hb levels

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 blood glucose strip for test.



STEP 2

Collect a blood sample for about 1.0 µL with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with 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.



PC I

100
mg/dL
HCT 58%
Hb 19.7 g/dL

STEP 3

After a few seconds, the meter will display your blood glucose test result with HCT/Hb levels. 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 litre 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 meals	< 140 mg/dL (7.8 mmol/L)

American Diabetes Association. Standards of medical care in diabetes- 2016; 39 (supp.1 Diabetes Care): S16.

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 :

- ▶ You first receive 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 5%
- > 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)

Hematocrit Range: 0 % to 70 %

Accuracy

The keto-mojo TD-4279 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 Keto-mojo TD-4279 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 in percent.

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%

Symbol Information

Symbol	Referent	Symbol	Referent
	<i>in vitro</i> diagnostic medical device		Keep away from sunlight
	Consult instructions for use		Keep dry
	Temperature limitation		Do not use if package is damaged
	Do not reuse		

Distributed by

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Please contact your healthcare provider outside hours of operation.

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



For self-testing.

35.6°F - 86°F