

β-Ketone Test Strips

Use only with GIMACARE Multi-Functional Monitoring System.

Warnings

- For in vitro diagnostic use (outside of the body) only.
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this manual and your GIMACARE Multi-Functional Monitoring System Owner's Manual before you begin. Only use GIMACARE β-Ketone Test Strips with GIMACARE Multi-Functional 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.
- For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results may not be a true reflection of the physiological β-Ketone level. It may apply under the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycemia, hyposmolar non-ketotic coma, shock, decompensated heart failure NYHA Class IV or peripheral arterial occlusive disease.
- Keep test strips and lancets away from young children. If swallowed, consult a doctor immediately for advice.

Intended Use

GIMACARE β-Ketone Test Strip is intended for the quantitative measurement of β-Ketone in venous whole blood and fresh capillary whole blood from finger. They are indicated for use at home or in clinical settings as an aid to monitor the effectiveness of diabetes control. Professionals may use test strips to test capillary and venous blood sample; home use is limited to capillary whole blood testing.

Limitations

- Use only heparin for anticoagulation of fresh capillary or venous whole blood.
- Hematocrit: The hematocrit level is limited to between 10% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- In vitro ascorbic acid up to 228 μmol/L, captopril up to 23 μmol/L, cholesterol up to 15 mmol/L, dopamine up to 5.8 μmol/L, gentisic acid up to 117 μmol/L, L-DOPA up to 10 mg/L, paracetamol up to 1324 μmol/L, triglycerides up to 30 mmol/L, uric acid up to 3 mmol/L, and unconjugated bilirubin up to 400 μmol/L, showed no interference.
- Altitude Effects: Altitudes up to 11,500ft (3,500m) do not affect test results.

Storage and Handling

- 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 2°C and 30°C (35.6°F and 86°F) and between 10% and 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



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

Calibration

Calibrate the meter every time whenever begin to use a new package of 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 your test strip vial label/packet.

Code Chip

1. Insert the code chip with the meter switched off. Wait until a number and "KET or KETONE" appears on display.
2. Remove the code chip. The display will show "OFF", and then the meter will automatically switch off.

Checking the Code Number

Make sure that the number and "KET or KETONE" displayed on the meter matches the number on your test strip vial label/packet before you proceed. If the numbers match, you can proceed with the test. If they do not match, please stop testing and insert the correct code chip. If the problem persists, contact customer service for help.

Testing Your β-Ketone

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING. ALWAYS REFER TO THE OWNER'S MANUAL AND LANCET INSERT ON HOW TO COLLECT A BLOOD SAMPLE.

1. Insert the test strip fully into the slot of your meter until it will not go any further. When the strip is fully inserted, the meter will perform several self-checks.
2. Collect a blood sample with the test strip. Make sure there is a sufficient quantity of blood in order to provide accurate test results. Apply the blood drop to the absorbent hole of the test strip, and wait until the confirmation window is fully filled. The meter will start counting down. Do NOT apply a smeared blood sample. NEVER try to add more blood to the test strip after the drop of blood has moved away.

3. After a few seconds, the meter will display your β-Ketone level. The last reading will be automatically saved in the meter. The meter will turn off automatically after the test strip is removed. Make sure to dispose the used lancet and test strip carefully.

The used lancet and test strip are potentially biohazardous. Please dispose them carefully according to your local regulations. Please refer to your Owner's Manual for further information.

Reading Your Result

The β-Ketone readings deliver plasma equivalent results and are displayed in millimoles of β-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.¹¹ 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 programme. 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).¹¹: Wiggam ML, 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.

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 expiration date of your test strips.
- Check the performance of your meter and test strip with the control solution.

Δ If your test results are significantly different from what you expect, or in unusually high or low

levels, please repeat the test with a new test strip or contact your healthcare professional.

Expiry Date Reminder

For your convenience, the expiry date reminder will activate and notify you the number of days remaining until the strip's expiry date shown on the vial label or on the foil packet. The count down begins from 30 days to 1 day, which will be shown at the center of the display screen. When you see the date reminder, please use the remaining test strips before they expire.

Δ The error message E-2 will appear in the following situations:

- The test strip is expired;
- The code chip is expired; or
- On the initial set-up, the date has been set incorrectly on the meter.

If the error message E-2 appears, please repeat the test with a new lot of test strip to get accurate results.

Chemical Components

β-Hydroxybutyrate Dehydrogenase (Pseudomonas sp.) ≥ 0.5 U

Mediator 55%

NAD ≥ 0.5 μg

Enzyme protector 8%

Non-reactive ingredients 29%

Quality Control Testing

Our control solutions contain a known amount of β-Ketone that will react with the test strips. If you are concerned about the meter or test strips are not working properly, you can check the performance of the meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the test strip package. Please refer to your Owner's Manual for the step-by-step quality control test instructions.

Δ 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

Additional Information

Always wear gloves and follow your local 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: 0.8 μL

Reaction Time: 10 seconds

System Measurement Range: 0.1 to 8.0 mmol/L

Hematocrit Range: 10% to 70%

Accuracy

The reference method is β-Hydroxybutyrate LiqueColor®. The reagent can quantitatively detect the presence of β-Ketone in patients with suspected diabetic ketoacidosis

β-Ketone	n = 480	
	Capillary samples	Range, mean
Regression	y = 0.9596x + 0.1524 R ² = 0.9913	Range: da 0.01 a 7.77 mmol/l Mean: 0.86mmol/L

β-Ketone	n = 480	
	Capillary samples	Range, mean
Regression	y = 0.9583x + 0.0306 R ² = 0.9811	Range: da 0.02 a 7.58 mmol/l Mean: 1.15mmol/L

User performance

β-Ketone	n = 160	
	Capillary samples	Range, mean
Regression	y = 0.9683x + 0.1407 R ² = 0.9853	Range: da 0.01 a 7.77 mmol/l Mean: 0.75mmol/L

Precision

β-Ketone	Concentration		
	0.5mmol/L	2.5mmol/L	5.0mmol/L
Mean	0.5	2.5	5.1
SD	0.042	0.065	0.115
CV (%)	---	2.65	2.27

Symbol Information

Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Humidity limitation
	Consult instructions for use or consult electronic instructions for use		Manufacturer
	Temperature limit		Model number
	Use-by date		Do not re-use
	Batch code		Unique device identifier
	Caution		CE mark
	Authorized representative in the European Community		

MedNet EC-REP GmbH
Borkstraße 10
48163 Münster, Germany

TaiDoc Technology Corporation
B1-7F, No.127, Wugong 2nd Rd.,
Wugu Dist.,
24888 New Taipei City, Taiwan
www.taidoc.com

Per l'autotest.
For self-testing.
Pour l'autocontrôle.
Para autodiagnóstico.



TD-4663