

CareTouch® β -Ketone Test Strip Manual

Intended Use

CareTouch® β -Ketone Test Strip, when used together with CareTouch® Blood Glucose and β -Ketone 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.

Limitations

- ▶ 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 Blood Glucose and β -Ketone Monitoring System Owner's Manual before you use this test strip. Use only CareTouch® Test Strips with CareTouch® Blood Glucose and β -Ketone Monitoring System to obtain accurate results, and 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.
- ▶ 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.
- ▶ Hematocrit: The hematocrit level is limited to between 20% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- ▶ Neonatal Use: **These test strips are not for use with neonates.**
- ▶ 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 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

The code chip is applied to calibrate the meter and set a reminder that the test strip will be expired in 30 days.



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.

STEP 1

Insert the code chip when the monitor is off. Wait until the number appears on the display.

STEP 2

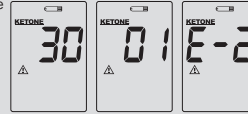
Remove the code chip. The display will show "OFF", and then meter will switch off. This means that the meter has been updated to the new expiry date and is ready for measurement.

Checking the Number

You need to make sure that the number displayed on the meter matches the number on your test strip vial or package 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 Service for help.

NOTICE:

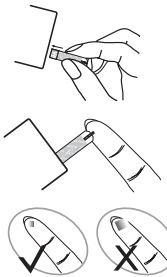
- The number on the display is only for your reference.
- The expiry date reminder will be activated and an error message will appear if the test strip is expired. The numbers in the center means that the day counts down from 30 to 01. Please be reminded to use the remaining test strips within 30 days to get accurate results. If the error message E-2 appears, it means that the test strip is expired. Repeat the test with a new lot of test strip to get accurate result.



Testing Your β -Ketone

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.

CAUTION: Lancing devices should never be used for more than one person.



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.

STEP 2

Collect a blood sample for about 1.0 μ L 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.

STEP 3

After a few seconds, the meter will display your β -Ketone level. 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. Dispose of used test strips according to their healthcare provider's instructions.

06
mmol/L

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 follow your healthcare provider's recommendations for proper disposal.

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.

β -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β -Ketone result is 0.0 mmol/L, 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).

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

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.

Questionable or inconsistent results

If the 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.

Quality Control Testing

Our control solutions contain a known amount of β -Ketone that can react with test strips. Perform a control solution test when:

- 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

- 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 of test strips. Make sure you check the range on the label of your current vial. 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 Service for assistance.

Chemical Components

- > β -Hydroxybutyrate Dehydrogenase (*Pseudomonas sp.*) ≥ 0.5 U
- > Mediator 55%
- > NAD ≥ 0.5 μ g
- > Enzyme protector 8%
- > Non-reactive ingredients 29%

Performance Characteristics

Sample Size: 1.0 μ L

Reaction Time: 10 seconds

System Measurement Range: 0.1 to 8.0 mmol/L

Hematocrit Range: 20% to 70%

Accuracy

CareTouch® system was tested in the hand of 120 lay users using capillary blood samples, covering the range 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 CareTouch® 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 in percentage.

Precision

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

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%

Symbol Information

Symbol	Referent
	<i>in vitro</i> diagnostic medical device
	Consult instructions for use
	Temperature limitation
	Do not use if package is damaged.

Symbol	Referent
	Keep dry
	Do not reuse
	Keep away from sun light
	Humidity limitation

Distributed by Future Diagnostics LLC
Future Diagnostics LLC
Brooklyn, NY 11220
1.866.890.8500
Hours of operation 9:00am-5:00pm EST

Use only with CareTouch® Blood Glucose and β -Ketone Monitoring System.



For self-testing