

FreeStyle

Optium β -Ketone

Blood β -Ketone Test Strips

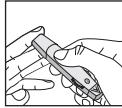
Read This First

IMPORTANT: Read these instructions for use and the User's Manual supplied with your meter before you monitor your blood β -Ketone. Failure to follow instructions will cause incorrect results.

English

What are my test strips for?

FreeStyle Optium Blood β -Ketone Test Strips are for use with FreeStyle Optium Neo, FreeStyle Optium, Optium and Optium Xceed Meters. (Not all products are available in all countries.) The test strips are designed to quantitatively measure blood β -Ketone (Beta-Hydroxybutyrate) in fresh capillary whole blood from the fingertip.



The test strips are for use outside the body (*in vitro* diagnostic use) and are for self-testing or healthcare professional use. Healthcare professionals may also use venous whole blood samples, provided the samples are used within 30 minutes of collection. These systems are not for use in diagnosis of diabetes mellitus, but are to be used as an aid in monitoring the effectiveness of diabetes control programmes.

What's in my test strip box?

- Test strips individually wrapped in purple foil packets
- Instructions for use

What else do I need that is not in my test strip box?

- FreeStyle Optium Neo, FreeStyle Optium, Optium or Optium Xceed Meter (Not all products are available in all countries.)
- MediSense or Optium Glucose and Ketone Control Solutions
- User's Manual
- Lancing device and disposable lancets

How do I check my meter?

Perform a control solution test when you question your results and want to confirm that your meter and test strips are working properly. For information on how to obtain control solutions, please contact Customer Services.

Control results must be within the "Expected Results for Use with Control Solutions" printed on these instructions for use.

How do I obtain a blood drop?

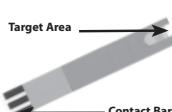
- Before you obtain a blood drop, make sure your fingertips are clean, dry, and warm. To warm your fingertips, wash your hands in warm water.
- Hang your arm down before lancing your fingertip, to help blood flow.
- Avoid excessive squeezing of your fingertips.
- Apply the blood drop to the test strip immediately.

How do I monitor my blood β -Ketone?

1. Remove the test strip from the purple foil packet. Open the test strip packet by tearing at the notch.



2. Insert the contact bars at the end of the test strip into the test port of the meter. Gently push the test strip in until it stops. The meter turns on automatically. **NOTE:** Optium and Optium Xceed Meter users should check that LOT 75001 or CODE 75001 appears on the meter display window. If LOT 75001 or CODE 75001 is not displayed, contact Customer Services.



3. Obtain a blood drop. Follow the instructions for use packaged with the lancing device.

4. Touch the blood drop to the white target area at the end of the test strip. The blood is drawn into the test strip.

What if the countdown does not start? The meter displays the blood β -Ketone result in 10 seconds. If the countdown does not start, you might not have applied enough blood to the test strip. Apply a second drop of blood to the test strip within 30 seconds of the first drop. If the countdown still does not start, or if more than 30 seconds have passed, discard the test strip, turn off your meter, and repeat steps 1 – 4.

You can use the opened foil packet to remove and discard your used blood β -Ketone test strip. Discard the test strip properly.

What does my result mean?

The blood β -Ketone test measures Beta-Hydroxybutyrate (β -OHB), the most important of the three ketone bodies in the blood¹. Normally, levels of β -OHB are expected to be less than 0.6 mmol/L². β -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill^{1,3}.

If your blood β -Ketone result is 0.0 mmol/L and your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, repeat both the ketone and the glucose tests 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 blood β -Ketone result is between 0.6 and 1.5 mmol/L and your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, this may indicate development of a problem that could require medical assistance. *Follow your healthcare professional's instructions.*

If your blood β -Ketone result is higher than 1.5 mmol/L and your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA)²⁻⁶.

IMPORTANT - How do I take care of my test strips?

- Use the test strip immediately after opening its foil packet.
- Your test strips should be stored at a temperature between 4° – 30°C (39° – 86°F). Storage outside this range may cause incorrect results. Keep away from direct sunlight and heat.
- Use each test strip once and then discard it.
- Do not use out-of-date test strips. Check the expiry date printed on the test strip box and on every test strip foil packet. If only the year and month are printed on the test strip, then the expiry date is the last day of month. For example, "EXP 2014/03" means the test strip expires on March 31, 2014.
- Do not use a test strip that is wet, bent, scratched or damaged.
- Do not use the test strip if its foil packet has a puncture or tear in it.
- Observe caution when using around children. Small parts may constitute a choking hazard.

What else do I need to know?

- The FreeStyle Optium Neo, FreeStyle Optium, Optium and Optium Xceed Systems can read blood β -Ketone levels between 0.0 and 8.0 mmol/L.
- Use FreeStyle Optium Blood β -Ketone Test Strips at temperatures between 18° – 30°C (64° – 86°F) and 10% and 90% relative humidity (the amount of moisture in the air) for best results.
- Clinical testing demonstrates that altitudes up to 2,195 metres (7,200 feet) above sea level do not affect results.

Are there important messages that I need to know about?

The following messages may indicate you have obtained a blood β -Ketone result that requires immediate action or there may be a problem with the test strip:

- **HI** means your meter has determined that your blood β -Ketone result is higher than 8.0 mmol/L.
- **Test Error 2 or Test Error 4** (Optium Meter) or **E-3 or E-4** (FreeStyle Optium Neo, FreeStyle Optium and Optium Xceed Meters) means there may be a test error.

If any of these messages show, repeat the test with a new test strip. If the same message shows again, contact your healthcare professional **immediately**. You may also perform a control solution test to check the performance of your system. Follow your healthcare professional's advice before you make any changes to your diabetes medication programme.

LOT

Expected Results for Use with Control Solutions

LO

Low:

MID

Mid:

HI

High:

 Abbott

Important Information for Healthcare Professionals

Note: Venous whole blood samples may be collected into sodium or lithium heparin tubes or EDTA tubes and used within 30 minutes. Do not use tubes containing fluoride or oxalate.

Limitations of Procedure

- This test strip has not been evaluated for alternative site testing.
- This test strip is not designed for use with arterial, neonatal, serum or plasma samples.
- Haematocrit range is 30%-60%.
- Test Results may be erroneously low if the patient is severely dehydrated, or severely hypotensive, in shock or in a hyperglycaemic-hyperosmolar state.
- The following substances have no significant effect on blood β -Ketone results:
 - Captopril up to 23 $\mu\text{mol/L}$ (500 $\mu\text{g/dL}$)
 - L-DOPA up to 30 $\mu\text{mol/L}$ (600 $\mu\text{g/dL}$)
 - Dopamine up to 5.9 $\mu\text{mol/L}$ (90 $\mu\text{g/dL}$)
 - Gentisic acid up to 117 $\mu\text{mol/L}$ (1.8 mg/dL)
 - Paracetamol up to 1.7 mmol/L (25 mg/dL)
 - Uric acid up to 1.4 mmol/L (24 mg/dL)
 - Ascorbic acid up to 227 $\mu\text{mol/L}$ (4 mg/dL)
 - Unconjugated bilirubin up to 342 $\mu\text{mol/L}$ (20 mg/dL)
 - Cholesterol up to 12.9 mmol/L (500 mg/dL)
 - Triglycerides up to 21.2 mmol/L (1875 mg/dL)

Test Principle

When the blood sample is applied to the test strip, the β -OHB in the blood reacts with the chemicals on the test strip, producing a small electrical current. This current is measured and a result is then displayed by the meter. The size of the current depends on the amount of β -OHB in the blood sample.

Composition

β -Hydroxybutyrate Dehydrogenase (<i>Pseudomonas sp</i>)	$\geq 0.03 \text{ U}$
NAD (Free acid form)	$\geq 1.67 \mu\text{g}$
Phenanthroline quinone	$\geq 0.29 \mu\text{g}$
Non-reactive ingredients	$\geq 19.51 \mu\text{g}$

Assay Range: 0.0 – 8.0 mmol/L

Test Time: 10 seconds

Sample Volume: 1.5 μL

Calibration Reference

The FreeStyle Optium Blood β -Ketone Test Strip is calibrated to reflect plasma β -hydroxybutyrate using the Randox assay kit (RB1007).

Precision

Precision testing shows that results typically vary by no more than 3.1% to 3.8%. Results were obtained in a laboratory study using venous whole blood samples (n = 20 per level). Please see Table 1.

Accuracy

Accuracy testing shows that results are comparable between trained operators and lay users. Accuracy was assessed at three clinics and four hospitals by comparing whole blood β -OHB results with plasma results obtained using a reference laboratory instrument. Please see Table 2. These studies show that the FreeStyle Optium Neo, FreeStyle Optium, Optium and Optium Xceed Systems compare well with the laboratory reference method.

Table 1 - Precision

	Low	Mid	High
Mean, mmol/L	0.34	2.36	6.32
SD, mmol/L	0.03	0.09	0.2
CV, %	–	3.8	3.1

Table 2 - Accuracy

No. of samples	288
Ketone Range, mmol/L	0.07-5.2
Slope	1.06
Intercept, mmol/L	0.07
r (corr. coef.)	0.98

Description of Symbols

	Consult instructions for use		Use by
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Batch code		Manufacturer
	Catalogue number		Do not reuse

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Product of UK.

References

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