

Optium™ Ketone

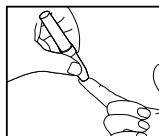
Blood β -Ketone Test Strips

Read This First

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

What are my test strips for?

Optium™ Ketone Blood β -Ketone Test Strips are for use with Optium™ and Optium™ Xceed™ sensors. 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.



What's in my test strip box?

- Test strips individually wrapped in foil packets
- 1 Instructions for use
- 1 Information card
- 1 Calibrator

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

- Optium or Optium Xceed sensor
- MediSense® Control Solutions
- User's Guide
- Lancing device and disposable lancets

IMPORTANT FIRST STEP: CALIBRATION

Why must I calibrate my sensor?

You must calibrate your sensor so it can recognize the test strip you are using. This ensures that your results are accurate. Failure to calibrate properly will cause incorrect results.

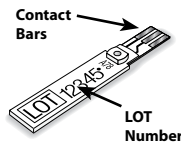
When should I calibrate my sensor?

You must calibrate your sensor each time you open and use a new box of test strips. Use only the calibrator that comes with the new box of test strips. When the box is empty, throw the calibrator away.

How do I calibrate my sensor?

1. Hold the calibrator with the LOT number facing toward you. Insert the calibrator into the test port. Push it in until it stops.
2. Check that the LOT number matches on all of these items: Sensor display window, test strip calibrator, test strip instructions for use, test strip foil packet.

Please note: Your sensor may display the word "CODE" with the LOT number. This number is the LOT number and must match on all items listed in step #2.



How do I check my system?

Use a MediSense Control Solution to do a control solution test when you question your results and want to confirm that your sensor and test strips are working properly. For information on how to obtain Control Solutions, please call Abbott Products Customer Service Freecall Number at 1800 801 478 (Australia) or 0800 106 100 (New Zealand).

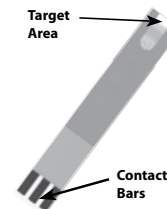
Control results must be within the "Expected Results for Use with MediSense Control Solutions" printed on these instructions for use.

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 its foil packet. The information card in your box of test strips shows how to open the foil packet.
2. Insert the contact bars at the end of the test strip into the test port of the sensor. Gently push the test strip in until it stops. The sensor turns on automatically.
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.



The sensor 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 sensor, 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 program.

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.

LOT

Expected Results for Use with MediSense Control Solutions

Low:

Mid:

High:

For Artwork and Packaging Department Use Only

Artwork File Name: DOC08060 Rev. A
Orig. Creation Date: 12/Apr/2006 By: TT
Last Modified date: 24/Apr/2006 By: TT
Software/Version: InDesign CS2

Dieline:

Bar Code:

Colors: Black

Fonts: Refer to collection report.

Slug 1205

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 expiration 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 expiration date is the last day of the month.
- 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.

What else do I need to know?

- The Optium™ and Optium™ Xceed™ sensors can read blood β-Ketone levels between 0.0 and 8.0 mmol/L.
- Use Optium™ Ketone 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 meters (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 sensor has determined that your blood β-Ketone result is higher than 8.0 mmol/L.
- If **Test Error 2** or **E-3** or **Test Error 4** or **E-4** shows in the display window, there may be a test error.

If any of these messages shows, check that your sensor is calibrated correctly and repeat the test with a new test strip. If the same message shows again, contact your healthcare professional **immediately**. You may also use a MediSense® Control Solution to check the performance of your system. Follow your healthcare professional's advice before you make any changes to your diabetes medication program.

References

1. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. *Special Topics in Endocrinology and Metabolism* 1982;4:1-27.
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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 noninsulin-dependent diabetes mellitus patients: The relationship to serum C-peptide immunoreactivity and free insulin. *Ann Nutr Metab* 1990;34:333-42.
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6. Hale PJ, Crase J, Nattrass M. Metabolic effects of bicarbonate in the treatment of diabetic ketoacidosis. *Br Med J* 1984;289:1035-8.

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Important Information for Healthcare Professionals

Note: Venous whole blood samples may be collected into sodium or lithium heparin 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.
- Hematocrit range is 30%-60%.
- The following substances have no significant effect on blood β-Ketone results:
 - Captopril up to 23 μmol/L (500 μg/dL)
 - L-DOPA up to 30 μmol/L (600 μg/dL)
 - Dopamine up to 5.8 μmol/L (90 μg/dL)
 - Gentic acid up to 117 μmol/L (1.8 mg/dL)
 - Acetaminophen 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 μmol/L (4 mg/dL)
 - Unconjugated bilirubin up to 342 μmol/L (20 mg/dL)
 - Cholesterol up to 12.9 mmol/L (500 mg/dL)
 - Triglycerides up to 17 mmol/L (1500 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 sensor. The size of the current depends on the amount of β-OHB in the blood sample.

Composition

β-Hydroxybutyrate Dehydrogenase (<i>Pseudomonas sp.</i>)	≥ 0.03 U
NAD (Free acid form)	≥ 1.67 μg
Phenanthroline quinone	≥ 0.29 μg
Non-reactive ingredients	≥ 19.51 μg

Performance Characteristics

The performance of Optium Ketone Blood β-Ketone Test Strips has been evaluated in both laboratory and clinical studies.

Assay Range: 0.0 - 8.0 mmol/L **Test Time:** 10 seconds

Sample Volume: 1.5 μL

Calibration Reference

The Optium Ketone 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 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	203
Ketone Range mmol/L	0.0-5.6
Slope	0.958
Intercept	-0.067
R (corr. coef.)	0.959

If you have any questions and/or need assistance, call Abbott Products Customer Service Freecall Number: 1800 801 478 (Australia), 0800 106 100 (New Zealand), or your local Abbott Diabetes Care office or distributor.