

Warnings

- ▶ For *in vitro* diagnostic use (for 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 has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- ▶ Please read this sheet and your 4SURE Smart Duo monitoring system Owner's Manual before you use this test strip. Use only 4SURE β-Ketone Test Strips with 4SURE Smart Duo 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.
- ▶ Please do not use 4SURE Smart Duo monitoring system on critically ill patients. The collection of capillary blood from the approved sample sites is not advised when the peripheral circulation is impaired as the delivery of physiological β-Ketone level might not be a true reflection. The following circumstances may apply: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycemic, hyperosmolar non-ketotic coma, shock, decompensated heart failure NYHA Class IV or peripheral arterial occlusive disease.
- ▶ Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

4SURE β-Ketone Test Strips, when used together with 4SURE Smart Duo monitoring system, allow your β-Ketone levels to be measured by yourself at home or by healthcare professionals. It uses fresh whole blood samples with following indication. Home use of β-Ketone testing requires capillary blood samples from the fingertip only. (Alternate site testing is not supported). In addition, health care professionals can also use venous blood samples, but arterial, neonatal and alternate site testing is not supported. For professional use of β-Ketone testing, only use heparin for anticoagulation of venous and capillary whole blood samples. This system is not intended for use in the diagnosis or screening of diabetes mellitus.

Limitations

- ▶ Hematocrit: The hematocrit level is limited to between 10% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- ▶ Neonatal Use: This test strip must not be used for the testing of newborns.
- ▶ This test strip is used for testing fresh capillary and venous blood.
- ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275 m) do not affect test results.
- ▶ Please see Appendix: Summary of substances and concentrations in excess of limitation with interference.

Storage and Handling

IMPORTANT: Do not use the test strips if they have expired.

- ▶ Test strips can be used from first opening until expiry date on vial.
- ▶ Store the test strips in a cool, dry place between 2 °C and 30 °C (39.2 °F and 86.0 °F) and below 85% relative humidity.
- ▶ Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- ▶ Avoid storing the test strips in kitchens or bathrooms.
- ▶ Do not touch the test strips with wet hands.
- ▶ Do not bend, cut, or alter the test strip.

Testing Your β-Ketone

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTS.



Please refer to your Owner's Manual for more information.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

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 β-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 strip. 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).¹⁻⁶

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 expiry date of the test strips.
- Check the performance of your meter and test strip with the control solutions.
- Make sure your monitor has correct coding, and the code is the same as the code printed on the individual foil packet you are using.

Please 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.

Quality Control Testing

Our control solutions contain a known amount of β-Hydroxybutyrate that can react with test strips. 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 individual foil pack. Checking regularly can ensure your test results are accurate. Please refer to the Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of the control solutions may vary with each new test strip. Make sure you check the range on the individual foil pack of your current test strip.

Chemical Components

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

Additional Information for Healthcare Professionals

Always wear gloves and follow your facility's 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 mmol/L to 8 mmol/L

Hematocrit Range: 10% to 70%

Performance

Accuracy

The table below displays how often 4SURE achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested three times which resulted in 480 test results) to see how well 4SURE performed compared to β-Hydroxybutyrate LiquiColor® reference method results.

Capillary samples (n=480)	β-ketone concentration (mmol/L)	Regression analysis
	Range: 0.10 to 6.75 Mean: 1.13	$y = 0.9997x - 0.0153$, $R^2 = 0.9912$
Venous samples (n=480)	β-ketone concentration (mmol/L)	Regression analysis
	Range: 0.10 to 6.75 Mean: 1.12	$y = 0.9926x - 0.0554$, $R^2 = 0.9772$

Precision

In repeatability test, the standard deviation (SD) is within 0.1 mmol/L for each β-Ketone concentration < 1 mmol/L and the coefficient of variation (CV) is less than 7.5% for each β-Ketone concentration ≥ 1 mmol/L.

Appendix

Table A summarizes the substance concentrations at which interference with β-Ketone measurement was greater than ±10% bias compared to the control test.

Substance	Concentration Tested
Captopril	23 μmol/L
L-DOPA	50 mg/L
Dopamine	5.87 μmol/L
Gentisic acid	117 μmol/L
Acetaminophen (Paracetamol)	1324 μmol/L
Uric acid	3 mmol/L
Ascorbic acid	228 μmol/L
Unconjugated bilirubin	400 μmol/L
Cholesterol	15 mmol/L
Triglycerides	30 mmol/L

Reference

- [1] Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism 1982;4:1-27.
- [2] Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood β-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997;20:1347-52.
- [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 noninsulindependent diabetes mellitus patients: The relationship to serum C-peptide immunoreactivity and free insulin. Ann Nutr Metab 1990;34:333-42.
- [5] Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. Diabetes 1988;37:1470-77.
- [6] Hale PJ, Crase J, Natrass M. Metabolic effects of bicarbonate in the treatment of diabetic ketoacidosis. Br Med J 1984;289:1035-8.

Symbol	Referent
	In vitro diagnostic medical device
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Use by
	Keep Dry
	Keep away from sunlight
	CE mark
	Batch code
	Humidity limitation
	Do not use if package is damaged
	Manufacturer
	Dispose of the packaging properly after use

For self-testing and point-of-care-testing of β-Ketone

Model No.: ACS053

Use Only With 4SURE Smart Duo monitoring system

NIPRO

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