KetoSens™ Blood *β*-Ketone Test Strips

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IMPORTANT
Please read this information and the *KetoSens/CareSens Dual Blood β-Ketone Meters Owner's Booklet* before using the KetoSens Test Strips.

INTENDED USE AND TEST PRINCIPLE

KetoSens Blood β-Ketone Test Strips work with the KetoSens/CareSens Dual Blood β-Ketone Meters to quantitatively measure β-Ketone in whole blood. The KetoSens/CareSens Dual Blood β-Ketone Monitoring Systems are for self-testing outside the body (*in vitro* diagnostic use). The KetoSens/CareSens Dual Blood β-Ketone Monitoring Systems should not be used for the diagnosis of diabetic ketoacidosis. β-Ketone in blood samples reacts with the chemical in the test strip to produce a small electrical current. The KetoSens/CareSens Dual Blood β-Ketone Meters detect the electrical current which reflects the amount of β-Ketone in the blood sample.

STORAGE AND HANDLING

- Store foil packet in a cool and dry place between 4-30°C. Do not freeze.
- Keep the foil packet of test strips away from direct sunlight or heat.
- Store unused test strips in their original foil packet to avoid damage or contamination.
- Handle test strips only with clean and dry hands.
- Use the test strip immediately after taking it out of the foil packet.
- Do not bend, cut, or alter the test strips in any way.
- Do not force a test strip into the meter. Gently push it into the meter's test strip port.
- Apply only fresh capillary whole blood for testing.
- Use all of the test strips within the expiration date printed on the foil packet.
- Dispose of test strips past the expiration date immediately. Using test strips past their expiration date can produce incorrect test results.
- Test strips in new, unopened foil packet can be used up until the expiration date printed on the foil packet if the test strips are used according to its storage and handling methods.

WARNINGS AND PRECAUTIONS

- Inaccurate results may occur in patients undergoing oxygen therapy.
- Keep test strips and the test strip box away from children. The test strips and foil packet may be choking hazards.
- Test strips are for single use only. Do not reuse.
- If the test strip does not absorb the blood sample properly, please contact your authorised i-SENS sales representative.

BLOOD SAMPLE COLLECTION PROCEDURE

Wash hands and sample site with soap and warm water. Rinse and dry thoroughly before collecting the blood sample with a lancing device.

Fingertip Site Blood Sampling

Unscrew the lancing device tip. Place the loaded lancing device against the side of the fingertip and press the release button. Massage the fingertip to obtain a round drop (at least 0.5 µL, actual size: ●) of blood. Apply test strip tip to the blood sample.

TEST PROCEDURE

1) Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.
2) Insert the test strip into the port with contact bars facing upwards. Push the strip in gently until the meter beeps.
3) The or symbol will appear.
4) Use lancing device to get blood sample. Sample must be at least 0.5 µL (actual size: ●) to fill the test strip confirmation window. When the or symbol appears on display, apply blood sample to edge of the narrow end of the test strip until the meter beeps. If the confirmation window is not filled completely, an Er4 message may appear.
5) Meter will count down from eight-to-one (8-to-1) on the display. Test result, time, and date will appear and automatically be stored in the meter's memory. Remove used test strip from port. Meter will turn off after three (3) seconds.

Please note that:

- An abnormally high or low red blood cell count (hematocrit level over 60% or below 30%) may produce inaccurate results.
- Severe dehydration (excessive water loss) may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Altitude of up to 3,000 m (10,000 ft) above sea level has no effect on the performance of the test strip.
- *Interferences:* Paracetamol, ascorbic acid (vitamin C), uric acid and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate high results.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- Discard used test strips properly in an appropriate container.

METER AND TEST STRIP PERFORMANCE CHECK

The KetoSens Control Solution (Control Low, Mid and/or High) contains a known amount of β-Ketone that reacts with the KetoSens Test Strip in combination with the KetoSens/CareSens Dual Meters to make sure they are working properly together and the correct testing procedure is being followed.

You may run a check when you:

- Want to practice the test procedure using the control solution instead of blood.
- Use the meter for the first time.
- Open a new box of test strips.
- Have symptoms that are inconsistent with your blood *β*-Ketone test results.
- Believe your test results are not accurate.
- Suspect your meter and test strips are not performing properly.
- Drop or damage the meter.

If your control solution test results do not fall within the range printed on the test strip box, repeat the test. Out of range results may be due to one or more of the following factors:

- Error in performing the test.
- Expired or contaminated control solution.
- Expired or damaged test strip.
- Failure to shake control solution bottle.
- Failure to discard first drop of control solution and wipe bottle tip clean.

If results continue to fall outside the range printed on the test strip box, the KetoSens Test Strip and the KetoSens/CareSens Dual Meters may not be working properly. If so, do not use your system and contact your authorised i-SENS sales representative.

CHEMICAL COMPOSITION

Each KetoSens Test Strip contains the following reagents:

Mediator: ≥ 1.5 µg
β-Hydroxybutyrate Dehydrogenase: ≥ 0.11 U
Other ingredients: ≥ 6.7 µg

PERFORMANCE CHARACTERISTICS

The performance of KetoSens BKM Systems has been evaluated in laboratory and in clinical tests.

ACCURACY

KetoSens BKM Systems are calibrated to yield results equivalent to plasma *β*-Ketone concentrations. The accuracy of the KetoSens BKM Systems (Model GM01GAA) was assessed by comparing whole blood *β*-Ketone results obtained by patients with those obtained using a reference laboratory instrument.

	KetoSens
Slope	0.9821
Y-intercept	0.0094
Correlation coefficient (r)	0.9969
Number of sample	100
Range tested	0.03-7.86

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PRECISION

Precision studies were performed in a laboratory using the KetoSens BKM Systems.

Within Run Precision		
Blood avg.	0.4 mmol/L	SD = 0.027 mmol/L
Blood avg.	1.1 mmol/L	SD = 0.056 mmol/L
Blood avg.	3.4 mmol/L	CV = 3.7%
Blood avg.	5.2 mmol/L	CV = 3.5%
Blood avg.	6.9 mmol/L	CV = 3.6%

Total Precision		
Control avg.	0.6 mmol/L	SD = 0.048 mmol/L
Control avg.	2.3 mmol/L	CV = 4.2%
Control avg.	3.9 mmol/L	CV = 4.0%

This study shows that there could be a variation of up to 4.2%.

For the performance data of all other models, please refer to your meter manual.
The model number can be found on the back of your meter.

DESCRIPTION OF SYMBOLS

	Consult instructions for use
	Temperature limitation
IVD	*In vitro* diagnostic medical device
	Manufacturer
LOT	Batch code
	Use by
	Cautions for safety and optimum product use
	Do not reuse
EC REP	Authorised representative

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