

KetoSens β -Ketone Control Solution

PKA1E1000 REV0 07/2016

IMPORTANT

- Please read the following information and the User's Manual of your meter before using the KetoSens Control Solution.
- Use the KetoSens Control Solution only with the KetoSens and CareSens Dual meters and their corresponding strips.

INTENDED USE

The KetoSens Control Solution is to be used to check that the KetoSens and CareSens Dual meters and the corresponding strips are working together properly and that you are performing the test correctly.

SUMMARY AND EXPLANATION

KetoSens Control Solution is a solution containing a specific amount of β -Ketone that is used to test meters and test strips in the KetoSens brand. The KetoSens Control Solution is for self-testing outside the body (*in vitro* diagnostic use). This solution may be used to check the performance of your meter and test strip or your testing technique. The test results you obtain should fall within the control solution range printed on the box of test strips that you are using.

CAUTION

The control solution ranges printed on the test strip box are for the KetoSens Control Solution only. These ranges are used to check the meter and test strip performance.

These are not recommended ranges for your blood β -Ketone level.

Use KetoSens β -Ketone Control Solution when:

- You want to practice the test procedure, without using blood.
- You use your KetoSens and CareSens Dual meters for the first time.
- You begin using a new box of test strips.
- You suspect that your meter or the strips are not working properly.
- You think your test results are inaccurate or do not reflect how you feel.
- You drop your meter.

STORAGE AND HANDLING

Store the KetoSens Control Solution at temperatures between 8-30°C/46- 86°F, tightly capped in the bottle. It must be kept at room temperature (20-25°C/68-77°F) before testing to obtain correct results. Do not refrigerate or freeze the control solution. Use before the expiration date shown on the bottle and within 3 months (90 days) of opening.

WARNING AND PRECAUTIONS


- The KetoSens Control Solution is for *in vitro* diagnostic use only.
- The KetoSens Control Solution is intended to be used only for self diagnostic testing of KetoSens and CareSens Dual meters and their corresponding strips.
- Use KetoSens Control Solution only with your KetoSens and CareSens Dual meters.
- Do not swallow or inject the control solution.
- Check the expiration date on the bottle. Do not use if expired.
- If the test results keep falling outside the specified range continually, do not use your system to test blood.
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20-25°C/68-77°F).
- Shake the bottle well before use, discard the first drop of solution, and wipe the tip with a clean tissue before applying the solution to the test strip.
- This solution contains a dye that may stain clothes.

TEST PROCEDURE

Step 1

Insert the test strip into the strip port of your meter.

Step 2

Activate the Control Solution Test Mode by pressing the ► button on the meter for 3 seconds. The  symbol will appear on the display.

Step 3

Shake the control solution vial well before using.

Step 4

Discard the first drop of control solution you squeeze and wipe the dispenser tip clean.

Step 5

Apply the control solution to the tip edge of the strip until the meter beeps.

Step 6

Test results appear after the meter counts down from 8 to 1.

Compare your control result with the appropriate control solution range printed on the test strip box. If the result falls within the specified range, you are ready to use the meter and the test strips to test your blood.

Step 7

Remove the used test strip from the port. The meter will turn off automatically. Please read the KetoSens and CareSens Dual meter's User's Manual for further information before using the KetoSens Control Solution.

INTERPRETATION OF OUT OF RANGE RESULTS

At room temperature, KetoSens Control Solution test results should fall within the control solution range printed on the test strip box about 95% of the time. Accurate results also depend upon the meter being properly coded to match the code number printed on each test strip box (if your meter is a coding meter). If your control solution test results do not fall within the expected 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:

- An error in the way you are doing the test.
- Expired or contaminated control solution.
- Damaged or outdated test strips.
- A problem with the meter.
- Control solution that is too warm or too cold.
- Failure to shake the control solution vial vigorously and to wipe the vial tip clean.

IMPORTANT









If you continue to get control solution test results that fall outside the range printed on the test strip box, the system may not be working properly. Do not use the system to test your blood. If you are unable to resolve the problem, contact your authorized i-SENS representative in your area.

CHEMICAL COMPOSITION

Each 4 mL foil packet of KetoSens Control Solution contains:

- D-3-Hydroxybutyrate
- Preservative
- FD&C blue dye
- Viscosity-adjusting agent

DESCRIPTION OF SYMBOL

| | |
|---|---|
|  | Consult instructions for use |
|  | Temperature limitation |
|  | <i>In vitro</i> diagnostic medical device |
|  | Manufacturer |
|  | Authorised Representative |
|  | CE Mark reg. IVDD 98/79/EC |
|  | Batch code |
|  | Use by |



i-SENS, Inc.
43, Banpo-daero 28-gil, Seocho-gu,
Seoul 06646, Korea
www.i-sens.com



Medical Technology Promedt
Consulting GmbH
Altenhofstrasse 80, D-66386
St. Ingbert, Germany

© 2016 i-SENS, Inc. All Rights Reserved.

  0123