Go-Keto

Ketone Control Solution
Package Insert

REF GK124-92AA	English

PRINCIPLE AND INTENDED USE

The Go-Keto Ketone Control Solution contains a known concentration of β-Ketone. It is used to confirm that your Go-Keto Blood Ketone Test Strips and Go-Keto Blood Glucose & Ketone Meter are working together properly and that you are performing the test correctly.
You should perform a Ketone quality control test:

- Before you first use your meter to test blood β-Ketone, to familiarize yourself with its operation.
- Before using a new vial of Go-Keto Blood Ketone Test Strips.
- When you suspect that the Go-Keto Blood Glucose & Ketone Meter or Go-Keto Blood Ketone Test Strips are not working properly.
- When you suspect that your blood β-Ketone test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.

Three levels of Ketone control solution are available labeled Control Solution 0, Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 0 or level 2 test.

COMPOSITION

Control solution 0 contains less than 0.01% β-Ketone (active ingredient), Control solution 1 contains less than 0.04% β-Ketone (active ingredient) and Control Solution 2 contains less than 0.06% β-Ketone (active ingredient), all with preservatives in an aqueous based mixture.

STORAGE AND HANDLING

- Store the control solution at room temperature, 5-30°C (41-86°F).
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.
  Note: The expiration date is printed in Year-Month-Date format.
- Each bottle of control solution can be used for 6 months after you first open it. Record this opened expiration date on the bottle label.

PRECAUTIONS

- For *in vitro* diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject. For self-testing and professional use.
- Shake well before using.
- Control solution tests are specified to be accurate only when tested between 10 and 40°C (50-104°F).
- The control ranges shown on the test strip vial are not a recommended range for your blood β-Ketone level. Your personal blood β-Ketone target ranges should be determined by your diabetes healthcare professional.
- Do not touch the end of the test strip to the control solution bottle. This could cause contaminants to enter the control solution bottle.
- Use only Go-Keto Ketone Control Solution with your Go-Keto Blood Glucose & Ketone Meter and Go-Keto Blood Ketone Test Strips.

MATERIALS PROVIDED

- Ketone Control Solution
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Blood Glucose & Ketone Meter
- Blood Ketone Test Strips

INSTRUCTIONS FOR USE

1. Power on the meter by inserting a new blood Ketone test strip. Refer to your User's Manual on how to record the result as a Ketone quality control test and for further details on operating the meter.
2. Shake the control solution bottle thoroughly.
3. Squeeze the control solution bottle gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface, shake again, and then use.
4. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop and ensure the strip get sufficient sample.
   Notes: Do not apply control solution to the test strip directly from the bottle.
   If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.
5. Read the result from the meter display.

EXPECTED RESULTS

Control solution test results should be within the control range. The ranges for CTRL 0, CTRL 1 and CTRL 2 are displayed on the test strip vial (or on the foil pouch). For confirmation of results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range, and Control Solution 2 tests should fall within the CTRL 2 range. If the test results with control solution fall within the specified control range, it indicates your Go-Keto Blood Glucose & Ketone Meter and Go-Keto Blood Ketone Test Strip are working together properly and you are performing the procedure correctly.
If the control solution test results do not fall within the respective ranges:

- Check the expiration date of the test strip and control solution. Make sure that neither the test strip vial nor the control solution bottle has been opened for more than 6 months. Discard any expired test strips or control solution.
- Confirm the temperature in which you are testing is between 10 and 40°C (50-104°F).
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Make sure the code number on the vial (or on the foil pouch) of test strips you are using matches the code number that appears on the meter display.
- Confirm that you are using Go-Keto Ketone Control Solution that was provided with your kit.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the Ketone quality control test with a new blood Ketone test strip. If your results still fall outside the control range indicated on the test strip vial label or on the foil pouch, your meter may not be working properly. DO NOT use the system to test blood. Contact your local distributor for help. For complete instructions, please refer to the User's Manual included with your meter. For additional questions or issues with this product, please contact your local distributor for help.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Lot Number	CTRL	Control Range
EC REP	Authorized representative in the European Community		Manufacturer	REF	Catalogue Number

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