

English



# Blood Ketone Control Solution Package Insert

## PRINCIPLE AND INTENDED USE

The **Keto-Mojo™** Blood Ketone Control Solution contains a known concentration of ketone. It is used to confirm that your **Keto-Mojo™** Blood Ketone Test Strips and **Keto-Mojo™ GKI** Multi-function Meter are working together properly and that you are performing the test correctly. You should perform a quality control test:

- At least once a week
- When you open a new box of test strip
- When you want to check the meter and test strips
- If your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- If you have dropped the meter
- Your test result does not match with how you feel

Two levels of control solution are available labeled Control Solution Normal (**CTRL 2**) and Control Solution High (**CTRL 3**). Control Solution 2 is sufficient for most of self-testing needs. Contact **Keto-Mojo** for information on purchasing control solutions.

## COMPOSITION

Control Solution Normal contains less than 0.05% ketone (active ingredient) and Control Solution High contains less than 0.10% ketone (active ingredient), two levels control solution with preservatives in an aqueous based mixture.

## STORAGE AND HANDLING

- Store the control solution at 2-30°C (36-86°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 expiration date that is shown on the bottle.

**Note:** All expiration dates are printed in Year-Month format. 2021-01 indicates January, 2021.

- The control solution will expire 6 months after the bottle is opened for the first time. Record this discard date on the bottle label.

**Note:** Discard the expired control solution according to local regulations.

## 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 15 and 40°C (59-104°F).
- The control ranges shown on the box or labels are not a recommended range for your blood ketone level. Your personal blood 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.
- Do not use the control solution if the package is damaged.
- Use only **Keto-Mojo™** blood ketone control solution with your **Keto-Mojo™ GKI** Multi-function meter and **Keto-Mojo™** blood ketone test strips.

## MATERIALS REQUIRED

- Control Solution
- Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Test Strips

## INSTRUCTIONS FOR USE

1. Power on the meter by inserting a new test strip. Refer to your meter's User's Manual details on operating the meter.
2. Shake the control solution bottle thoroughly. 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.
3. Squeeze out a second small drop on to a clean, nonabsorbent surface and immediately touch the sample tip of the test strip to the control solution drop until the meter beeps.

**Notes:** Do not apply control solution to the test strip directly from the bottle.

If the control solution sample does not completely fill the check window, do not add a second drop.

Discard the test strip and start over with a new test strip.

4. Read the result from the meter display after 10 seconds.

## EXPECTED RESULTS

Control solution test results should be within the control range. The ranges for 2 levels (**CTRL 2** and **CTRL 3**) are displayed on the strip box or labels. For confirmation of results, Control Solution Normal tests should fall within the **CTRL 2** range, and Control Solution High tests should fall within the **CTRL 3** range. If the test results with control solution fall within the specified control range, it indicates your **Keto-Mojo™ GKI** Multi-function Monitoring System is working properly and you are performing the procedure correctly.

If the control solution tests results do not fall within the respective range:

- Check the expiration date of the test strip and *control* solution. Make sure that the control solution bottle has not 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 15 and 40°C (59-104°F).
- Make sure that the control solution bottle have been tightly capped.
- Confirm that you are using **Keto-Mojo™** blood ketone control solution.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the kit box or labels, your meter may not be working properly. **DO NOT** use the system to test blood. Contact **Keto-Mojo** for support.

For complete instructions, please refer to the User's Manual included with your meter. For additional questions or issues with this product, please contact **Keto-Mojo** for support.

## INDEX OF SYMBOLS

	Consult instructions for use		Use by		Catalog number		For <i>in vitro</i> diagnostic use only
	Lot number		Control range		Manufacturer		Temperature limitations
		Authorized Representative			Use by 6 months from the opening		



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