



## Blood $\beta$ -Ketone Control Solution Package Insert

### PRINCIPLE AND INTENDED USE

The **Keto-Mojo**<sup>®</sup> Blood  $\beta$ -Ketone Control Solution contains a known concentration of  $\beta$ -ketone. It is used to confirm that your **Keto-Mojo**<sup>®</sup> Blood  $\beta$ -Ketone Test Strips and **Keto-Mojo**<sup>®</sup> **GK+** Blood Glucose and  $\beta$ -Ketone 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
- Before using a new package of test strips
- When you suspect that the meter or test strips are not working properly
- If you suspect your meter is damaged
- If you dropped the meter
- When you suspect your test result is not accurate. Or if your test result does not match with how you feel

Two levels of control solution are available: Control Solution 2 (Level 2) and Control Solution 3 (Level 3). Control Solution 2 (Level 2) is sufficient for most of self-testing needs. If you think your meter or strips may not be working correctly, you may also want to perform Level 3 tests. If you want to purchase more control solution go to [shop.keto-mojo.com](http://shop.keto-mojo.com). Please contact **Keto-Mojo** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.

### COMPOSITION

Control Solution 2 contains less than 0.05%  $\beta$ -ketone (active ingredient) and Control Solution 3 contains less than 0.10%  $\beta$ -ketone (active ingredient). Two levels control solution have preservatives in an aqueous based mixture.

### STORAGE AND HANDLING

- Store the control solution between 36-86°F. Store at 10-90% humidity.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the expiration date. The date is shown on the bottle.

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

- Use the control solution only for 6 months after you first open it or before the expiration date, whichever comes first. The control solution will expire 6 months after the bottle is opened for the first time. Record this opened date on the bottle label and make note of the expiration date.

### PRECAUTIONS

- For *in vitro* diagnostic use. The control solution is for testing outside the body only. Do not swallow or inject. For self-testing use.
- Shake well before using.
- To get accurate results, perform control solution testing between 59-104°F.
- The control ranges are shown on the test strip or meter box or label. The control ranges are not a recommended range for your blood  $\beta$ -ketone level. Figure out your personal blood  $\beta$ -ketone target ranges with your 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**<sup>®</sup> Blood  $\beta$ -ketone Control Solution with your **Keto-Mojo**<sup>®</sup> **GK+** Blood Glucose and  $\beta$ -ketone Meter and **Keto-Mojo**<sup>®</sup> Blood  $\beta$ -ketone Test Strips.
- Always wash your hands well with soap and water before and after testing, when handling the meter and safety lancets or test strips.

### MATERIALS REQUIRED

- Control Solution
- Package Insert

If you want to purchase more control solution, or you want more information, please go to [keto-mojo.com/help-center](http://keto-mojo.com/help-center) or contact **Keto-Mojo** Customer Support at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.

### MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Test Strips

### INSTRUCTIONS FOR USE

1. Insert a new test strip. The meter turns on. Refer to your meter's User's Manual for more details.
2. Shake the control solution bottle thoroughly.
3. Squeeze the control solution bottle gently. 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 tip of the test strip to the control solution drop until the meter beeps.

**Notes:** Test immediately after the control solution has been squeezed.

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

If the control solution sample does not completely fill the sample tip, do not add a second drop. Discard the test strip. Start with a new test strip.

5. Read the result from the meter display after a beep.
  - Note:** The meter will automatically recognize the control test and it will not be included in 7, 14, and 30-day averages.

### EXPECTED RESULTS

Control solution test results should be within the control range. The ranges for two levels (Level 2 and Level 3) are displayed on the test strip or meter box or label. For confirmation of results, Control Solution 2 tests should fall within the level 2 range, and Control Solution 3 tests should fall within the level 3 range. If the test results are in the respective ranges, this means your **Keto-Mojo**<sup>®</sup> **GK+** Blood Glucose and  $\beta$ -Ketone Monitoring System is working correctly, and you are following the procedure properly. 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.
  - Make sure you are testing at a temperature between 59-104°F.
  - Make sure that the control solution bottle has been tightly capped.
  - Make sure that the test strip is used immediately after removing it from the test strip foil pouch.
  - Confirm that you are using **Keto-Mojo**<sup>®</sup> Blood  $\beta$ -ketone Control Solution with your **Keto-Mojo**<sup>®</sup> **GK+** Blood Glucose and  $\beta$ -ketone Meter and **Keto-Mojo**<sup>®</sup> Blood  $\beta$ -ketone Test Strips.
  - Make sure that you followed the test procedure correctly.
- After checking everything listed above, repeat the control solution test with a new test strip. If your results still fall outside the range indicated on the test strip box or label, your meter may not be working properly. **DO NOT** use the system to test blood. If you cannot correct the problem, contact **Keto-Mojo** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your healthcare professional if you need help outside of these hours.

Manufactured for: **Keto-Check, Inc.**  
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Number: 1205097102  
 Effective date: 2020-07-07