English

Blood β-Ketone Test Strips Package Insert

PRINCIPLE AND INTENDED USE

The **Keto-Mojo**® Blood β-Ketone Test Strips are thin strips. The strips have a chemical reagent system. They work with the **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Meter to measure the β-ketone level in fresh capillary whole blood. The test principle of the β-ketone is based on the amperometric detection of β-hydroxybutyrate (also known as 3-hydroxybutyrate) in whole blood. β-hydroxybutyrate is converted by the enzyme β-hydroxybutyrate dehydrogenase to acetoacetate. The magnitude of electrical current resulting from the reaction is proportional to the amount of beta-hydroxybutyrate present in the sample.

The **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Monitoring System is comprised of the **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Meter, the **Keto-Mojo**® Blood Glucose Test Strips and the **Keto-Mojo**® Blood β-Ketone Test Strips. The System is intended to quantitatively measure the glucose and β-ketone concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for at home self-testing outside the body (*in vitro* diagnostic use) by people with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended to be used by a single person and should not be shared.

The **Keto-Mojo**® Blood β-Ketone Control Solution is for use with the **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Meter and **Keto-Mojo**® Blood β-Ketone Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

COMPOSITION

Each test strip contains the following reactive chemicals: beta-hydroxybutyrate dehydrogenase (HBDH) <10 IU, Mediator <100 µg.
Each test strip pouch contains a drying agent.

STORAGE AND HANDLING

- Store test strips between 36-86°F. Store at 10-90% humidity. Avoid heat and direct sunlight.
- Use the test strips at temperatures between 45.5-113°F. Use the test strips between 10-90% humidity.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Use the test strip immediately after removing it from the foil pouch.
- Repeated insertion and removal of a test strip into the strip port may result in reading errors.
- Do not use your test strips beyond the expiration date (printed on the foil pouch). Otherwise, you may get incorrect test results.
  Note: *All expiration dates are printed in Year-Month format: 2021-01 indicates January 2021.*
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test strips away from children. Do not swallow test strips.
- Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection.
- Please refer to the User's Manual for complete cleaning and disinfection information.

PERFORMING A BLOOD KETONE TEST

Material provided: Keto-Mojo® Blood β-Ketone Test Strips and package insert.
Material required but not provided: Keto-Mojo® **GK+** Blood Glucose and β-Ketone Meter, User's manual, Lancing device, lancets and **Keto-Mojo**® Blood β-Ketone Control solution.
Refer to your User's Manual for complete instructions for blood sample collection before use.

1. Select the punch site. Wash your hands in warm, soapy water, dry your hands thoroughly.
2. Prepare the lancing device and lancets.
3. Check the expiration date. The expiration date is printed on the test strip foil pouch. Do not use test strips past the expiration date.
4. Insert the test strip into the meter. The meter turns on.
5. Lance the punch site to obtain a round drop of blood.
6. Touch the blood drop to the strip tip until the meter beeps. Do not apply blood on the top of test strip.
7. Your blood β-ketone test result will appear after the meter counts down from 9 to 1.

TESTING WITH CONTROL SOLUTION

Use only **Keto-Mojo**® Blood β-Ketone Control Solutions.
For complete details about checking the system, refer to your User's Manual.
When to check:

- At least once a week
- Before using a new box of test strip
- You want to check the meter and test strips
- Your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- 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

You should confirm your control solution results. Make sure the Control Solution 2 tests fall within the Level 2 range. Make sure the Control Solution 3 tests fall within the Level 3 range. Repeat control solution test with a new strip. **CAUTION:** If your control test result falls outside the control range, **DO NOT** use the system to test your blood, the system may not be working properly. 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.

LIMITATIONS

- For single patient use only.
- Very high (above 65%) and very low (below 20%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Do not use this system if you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) since it could cause your glucose and ketone results to be incorrect.
- The effect of oxygen therapy on the results of this system has not been studied.
- Not for use in patients with severe dehydration.
- Not for neonatal use.
- Not for use on patients with critical illness.
- Not for use in severely hypotensive individuals or on patients in shock or in a hyperosmolar state.
- The system should not be used following xylose absorption procedures
- Not for screening or diagnosis of diabetes.
- Do not use at altitudes above 13,123 ft (4,000 meters) above sea level.
- Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
- For *in vitro* diagnostic use only.
- The meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

PERFORMANCE CHARACTERISTICS

Repeatability, Precision

Repeatability-Blood			
Interval	β-Ketone concentration	Standard Deviations (SD)	Coefficient of Variation (CV)
1	0.32 mmol/L	0.04 mmol/L	11.4%
2	1.30 mmol/L	0.06 mmol/L	4.7%
3	2.34 mmol/L	0.09 mmol/L	3.8%
4	4.37 mmol/L	0.16 mmol/L	3.6%
5	6.76 mmol/L	0.24 mmol/L	3.6%
Intermediate Precision-Control Solution			
Interval	β-Ketone concentration	Standard Deviations (SD)	Coefficient of Variation (CV)
1	0.61 mmol/L	0.04 mmol/L	6.5%
2	2.23 mmol/L	0.08 mmol/L	3.5%
3	4.48 mmol/L	0.17 mmol/L	3.8%

Consumers Accuracy Study

The numbers and percentages represented in the below tables are the number of meter results compared to a laboratory result.
102 lay persons tested the capillary blood using the **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Meter (y). The blood was taken from fingertip.
Blood samples from different subjects were also analyzed with Randox RX Imola Chemistry Analyzer (x). The results were compared.

Linear Regression Results **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Meter (y) vs. Randox RX Imola Chemistry Analyzer (x)				
Sample Site	Slope	Intercept (mmol/L)	R	N
Fingertip	1.0037	-0.0083	0.9927	102

The blood β-ketone concentration range was 0.11 to 1.52 mmol/L for **Keto-Mojo**® **GK+** Blood Glucose and β-Ketone Meter testing with blood sample from fingertip test sites.

Fingertip Site: Consumers Accuracy Results			
Accuracy Results for Blood β-Ketone Concentration ≥1.5 mmol/L			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)
Accuracy Results for Blood β-Ketone Concentration <1.5 mmol/L			
Within ±0.1 mmol/L	Within ±0.2 mmol/L	Within ±0.3 mmol/L	
101/101 (100%)	101/101 (100%)	101/101 (100%)	

Accuracy Results for Blood β-Ketone Concentration ≥1.5 mmol/L	
Accurate Results (Meter result is +/- 20% of laboratory result)	1 out of 1 (100% of results)
Accurate Results (Meter result is +/- 15% of laboratory result)	1 out of 1 (100% of results)
Accurate Results (Meter result is +/- 10% of laboratory result)	1 out of 1 (100% of results)
Accurate Results (Meter result is +/- 5% of laboratory result)	1 out of 1 (100% of results)
Accuracy Results for Blood β-Ketone Concentration <1.5 mmol/L	
Accurate Results (Meter result is +/- 0.3 mmol/L of laboratory result)	101 out of 101 (100% of result)
Accurate Results (Meter result is +/- 0.2 mmol/L of laboratory result)	101 out of 101 (100% of result)
Accurate Results (Meter result is +/- 0.1 mmol/L of laboratory result)	101 out of 101 (100% of result)

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** at 800-513-1965 (5 days a week, 10am-4pm PST) for further assistance. Please contact your health care professional if you need help outside of these hours.

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