

English



Blood Glucose Test Strips Package Insert

PRINCIPLE AND INTENDED USE

The **Keto-Mojo**[®] Blood Glucose 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 glucose level in fresh capillary whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the meter. The amount of glucose is then calculated based on this current. The result is shown on the meter display. The meters are calibrated to display plasma equivalent results.

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 (beta-hydroxybutyrate) 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 Glucose Control Solution is for use with the **Keto-Mojo**[®] **GK+** Blood Glucose and β -Ketone Meter and **Keto-Mojo**[®] Blood Glucose 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

These chemicals are: Glucose Oxidase (from *Aspergillus Niger*) <25 IU, Mediator <300 μ g, Buffer, and Non-reactive Ingredient. 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 41-113°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 past the expiration date (printed on the strip foil pouch), or discard date. 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 strip foil pouch 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 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 GLUCOSE TEST

Materials provided: **Keto-Mojo**[®] Blood Glucose Test Strips and package insert.

Materials required but not provided: **Keto-Mojo**[®] **GK+** Blood Glucose and β -Ketone Meter, User's Manual, Lancing device, lancets and **Keto-Mojo**[®] Blood Glucose Control Solution.

See 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 glucose test result will appear after the meter counts down from 5 to 1.

CHECKING THE SYSTEM

Use only **Keto-Mojo**[®] Blood Glucose 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
- When you suspect that the meter or test strips are not working properly.
- If you suspect your meter is damaged.
- 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 health care professional if you need help outside of these hours.

LIMITATIONS

- For single patient use only.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- If you are taking vitamin C (ascorbic acid in your blood >3 mg/dL), your glucose results using this meter may not be reliable.
- Patients undergoing oxygen therapy may cause false results.
- Not for use on critically ill patients.
- Not for use on patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis).
- The **Keto-Mojo**[®] **GK+** Blood Glucose and β -Ketone Dual Monitoring System should not be used following xylose absorption procedures.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use in hypotensive individuals.
- Do not use at altitudes above 13,123ft (4,000 meters) above sea level.
- 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. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

PERFORMANCE CHARACTERISTICS

Repeatability, Precision

Repeatability-Blood		
Interval	Glucose concentration	Coefficient of Variation (CV)
1	49.5 mg/dL	4.6%
2	78.1 mg/dL	3.2%
3	133.5 mg/dL	3.0%
4	200.7 mg/dL	2.9%
5	357.5 mg/dL	2.8%
Intermediate Precision-Control Solution		
Interval	Glucose concentration	Standard Deviation (SD) or Coefficient of Variation (CV)
1	50.5 mg/dL	4.8%
2	117.5 mg/dL	2.7%
3	360.0 mg/dL	2.4%

Consumers Accuracy Study

The numbers and percentages represented in the below tables are the number of meter results compared to a laboratory result.

352 lay persons tested the capillary blood using the **Keto-Mojo**[®] **GK+** Blood Glucose and β -Ketone Meter (y). The blood was taken from fingertip. Fingertip blood samples from different subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results				
Keto-Mojo [®] GK+ Blood Glucose and β -Ketone Meter (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mg/dL)	R	N
Fingertip	0.9960	-0.2740	0.9974	352

Fingertip blood samples were used for YSI reference measurement. The glucose concentration range was 38.6 to 548.9 mg/dL for **Keto-Mojo**[®] **GK+** Blood Glucose and β -Ketone Meter testing with blood sample from fingertip test sites.

Fingertip Site: Consumer Accuracy Results			
Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
217/352 (61.6%)	336/352 (95.5%)	352/352 (100%)	352/352 (100%)

Accurate Results (Meter result is +/- 15% of laboratory result)	352 out of 352 (100% of results)
More Accurate Results (Meter result is +/- 10% of laboratory result)	336 out of 352 (95.5% of results)
Most Accurate Results (Meter result is +/- 5% of laboratory result)	217 out of 352 (61.6% of results)

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 healthcare professional if you need help outside of these hours.

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