

Blood Glucose Test Strips Package Insert

PRINCIPLE AND INTENDED USE

The **Keto-Mojo**TM Blood Glucose Test Strips are thin strips with a chemical reagent system. They work with the **Keto-Mojo**TM **GKI** Multi-function meter as a system to quantitatively measure the glucose concentration in fresh capillary whole blood. The Keto-Mojo[™] blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose enzyme and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed. The meter is calibrated to display plasma-like concentration results. The **Keto-Mojo™ GKI** Multi-function Monitoring System is in full compliance with the new EN ISO 15197:2015 International Standard.

The Keto-Mojo™ Blood Glucose Test Strips and Keto-Mojo™ GKI Multi-function meters are intended for use outside the body (in vitro diagnostic use) for self-testing and health care professional use, as an aid to monitor the effectiveness of diabetes control. The system should not be used for diagnosis of diabetes. Professionals may also test neonatal, venous and arterial blood samples.

COMPOSITION

Each test strip contains the following reactive chemicals: glucose dehydrogenase (GDH-FAD) < 25 IU, Mediator < 300 μg. Each test strip pouch contains a drying agent

STORAGE AND HANDLING

- Store test strips in a cool, dry place between 2-30°C (36-86°F). Keep away from heat and direct sunlight. Exposure to temperature and / or humidity outside the required condition may result in inaccurate readings.
- · Do not freeze or refrigerate
- Use the test strips at temperatures between 5-45°C (41-113°F).
- Use the test strips between 10-90% humidity.
- 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.
- Do not use your test strips beyond the expiration date (printed on the strip foil pouch), whichever comes first, because they may cause 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 change to your diabetes control program without speaking to your healthcare professional.

PERFORMING A BLOOD GLUCOSE TEST

Materials provided: **Keto-Mojo**[™] Test Strips and package insert Materials required but not provided: **Keto-Mojo**[™] **GKI** Multi-function meter, User's Manual, lancing device, clear cap (optional) and a new sterile lancet Refer to your User's Manual for complete instructions for blood sample collection hefore use

- Wash your hands in with warm water and soap, dry them thoroughly
- Prepare the lancing device
- Check the expiration date (printed on the strip foil pouch). Do not use test strips beyond the expiration date
- Insert the test strip into the meter in the direction of the arrows. The meter
- Using a lancing device and new lancet to obtain a round drop of blood.
- Touch the blood drop to the strip tip until the meter beeps. Do not apply blood on the top of test strip.

Your blood glucose test result will appear after the meter counts down from 5 to 1. IMPORTANT: The Keto-Mojo™ GKI Multi-function Monitoring Systems allows alternative site testing for forearm and palm testing in additional to fingertip testing. There are important differences between forearm, palm and fingertip samples that you should know. Important information about forearm and palm glucose testing:

- . When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

EXPECTED DIABETES CONTROL GOAL

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or exercise.

The American Diabetes Association suggests the following targets for most non-pregnant adults with diabetes. More or less stringent glycemic goals may be appropriate for each individual. In real life, consult your health care professional for the target value that is appropriate for you.

Expected blood glucose levels for most non-pregnant adults with diabetes:

pected blood glacose levels for most non-pregnant addits with diabetes.					
Time	Range, mg/dL	Range, mmol/L			
Before a meal	70 – 130	3.9 - 7.2			
1-2 hours after beginning of the meal	Less than 180	Less than 10			

Questionable or Inconsistent Results: Repeat the test according the procedures described in your Keto-Mojo™ GKI Multi-function meter User's Manual. If attempts to correct a problem fail, contact your health care nrofessional

CHECKING THE SYSTEM

Use only Keto-Moio™ Control Solutions.

For complete details about checking the system, refer your User's Manual When to check:

- 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

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. When testing with Control Solution Normal, make sure you are matching the results to the CTRL 2 range printed on the strip box or labels.

CAUTION: If your quality control test result falls outside the control range shown on the strip box or labels. DO NOT use the system to test your blood, as the system may not be working properly. If you cannot correct the problem, contact Keto-Mojo for further assistance.

LIMITATIONS

- The Keto-Mojo[™] GKI Multi-function meter, Keto-Mojo[™] Test Strips and Control Solution have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- · Fresh capillary blood may be collected into test tubes containing sodium heparin, lithium heparin if the blood is used within 10 minutes. Do not use sodium fluoride/oxalate or other anticoagulants or preservatives.
- Use only with whole blood. Do not use with serum or plasma samples.
- . Very high (above 70%) and very low (about 0%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit
- . Abnormally high levels of vitamin C and xylose and other reducing substances will produce false high blood glucose measurements.
- . The system is tested to accurately read the measurement of glucose in whole blood within the range of 10 to 600 mg/dL (0.6-33.3 mmol/L).
- · Fatty substances (triglycerides up to 3,000 mg/dL (166.7 mmol/L) or cholesterol up to 500 mg/dL (27.7 mmol/L)) have no major effect on blood glucose test
- The Keto-Mojo[™] GKI Multi-function Monitoring Systems has been tested and shown to work properly up to 10,000 ft (3,048 meters).
- Severely ill persons should not run the glucose test with the Keto-Mojo™ GKI Multi-function Monitoring Systems.
- . Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with **Keto-MojoTM GKI** Multi-function
- . Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of materials.

PERFORMANCE CHARACTERISTICS

The Keto-Moio[™] GKI Multi-function meter is calibrated by using YSI (Model 2300) STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.

Repeatability, Precision

	Repeatability-Blood				
Interval	Glucose concentration	Standard Deviation (SD) or Coefficient of Variation (CV)			
1	40.0 mg/dL (2.2 mmol/L)	1.3mg/dL (0.072mmol/L)			
2 76.9 mg/dL (4.3 mmol/L) 2.0mg/dL (0.111n		2.0mg/dL (0.111mmol/L)			
3	133.9 mg/dL (7.4 mmol/L)	1.8%			
4	194.9 mg/dL (10.8 mmol/L)	2.2%			
5	355.1 mg/dL (19.7 mmol/L)	2.0%			
	Intermediate	Precision-Control Solution			
Interval	Glucose concentration	Standard Deviation (SD) or Coefficient of Variation (CV)			
1	40.0 mg/dL (2.2 mmol/L)	1.5 mg/dL (0.08 mmol/L)			
2 119.8 mg/dL (6.7 mmol/L) 2.1%		2.1%			
3	3 349.9 mg/dL (19.4 mmol/L) 2.1%				

The capillary blood glucose measurements from 110 participants were taken by a trained technician using the Keto-Mojo™ GKI Multi-function meter with 3 strip lots (y). Capillary blood samples were obtained from fingertip, palm and forearm sampling sites for the **Keto-Mojo[™] GKI** Multi-function meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: Keto-Mojo™ GKI Multi-function meter (y) vs. YSI Reference (x)						
Sample Site Slope Intercept (mg/dL)/ (mmol/L) R				N		
Fingertip	1.0439	-5.3448/-0.2969	0.9926	220		
Palm	1.0275	-6.6310/-0.3684	0.9889	220		
Forearm	1.0338	-5.2924/-0.2940	0.9897	220		

Fingertip samples were used for YSI reference measurement. The sample range was 45.9 to 417 mg/dL (2.6 to 23.2 mmol/L) for Keto-Mojo™

GKI Multi-function meter testing

ŭ .				
Fingertip Site: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)				
Within \pm 5% Within \pm 10% Within \pm 15%				
72/150 (48.0%)	150/150 (100%)			
Fingertip Site: System Accuracy Results for Glucose Concentration < 100 mg/dL (5.5 mmol/L)				
Within ± 5 mg/dL (0.28 mmol/L)	Within ± 10 mg/dL (0.56 mmol/L)	Within ± 15 mg/dL (0.83 mmol/L)		
41/70 (58.6%)	70/70 (100%)			

Palm Site: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)				
Within ± 5%	Within ± 15%			
67/150 (44.7%)	150/150 (100%)			
Palm Site: System Accuracy Results for Glucose Concentration < 100 mg/dL (5.5 mmol/L)				
Within ± 5 mg/dL(0.28 mmol/L)	Within ± 15 mg/dL(0.83 mmol/L)			
36/70(51.4%)	65/70(92.9%)	70/70 (100%)		

Forearm Site: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)				
Within ± 5%	Within ± 15%			
71/150(47.3%)	127/150 (84.7%)	150/150 (100%)		
Forearm Site: System Accuracy Results for Glucose Concentration < 100 mg/dL (5.5 mmol/L)				
Within ± 5 mg/dL (0.28 mmol/L) Within ± 10 mg/dL (0.56 mmol/L) Within ± 15 mg/dL(0.83 mm				
40/70 (57.1%)	63/70 (90.0%)	70/70 (100%)		

Pregnant woman Study

The pregnant woman blood glucose measurements were taken by a trained technician using the **Keto-Moio[™] GKI** Multi-function meter (v). The pregnant woman blood samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below

Pregnant woman: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)				
Within ± 5%	Within ± 15%			
184/366 (50.3%)	311/366 (85.0%)	366/366 (100%)		
Pregnant woman: System Accu	ration < 100 mg/dL (5.5 mmol/L)			
Within ±5 mg/dL(0.28 mmol/L)	Within ±10 mg/dL(0.56 mmol/L)	Within ±15 mg/dL(0.83 mmol/L)		
46/74 (62.2%)	63/74 (85.1%)	74/74(100%)		

Neonatal Study

The neonatal blood glucose measurements were taken by a trained technician using the Keto-Mojo TM GKI Multi-function meter (y). The neonatal blood samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Neonatal: System Accuracy	Results for Glucose Concentratio	n ≥ 100 mg/dL (5.5 mmol/L)	
Within ± 5% Within ± 10%		Within ± 15%	
102/188 (54.3%)	152/188 (80.9%)	188/188 (100%)	
Neonatal: System Accuracy Results for Glucose Cond		n < 100 mg/dL (5.5 mmol/L)	
Within ±5 mg/dL(0.28 mmol/L)	Within ±10 mg/dL(0.56 mmol/L)	Within ±15 mg/dL(0.83 mmol/L)	
117/252(46.4%)	203/252(80.6%)	252/252(100%)	

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 further assistance

REFERENCES

1. ADA Clinical Practice Recommendations, 2014

	INDEX OF SYMBOLS					
\bigcap i	Consult instructions for use	2	Use by	Σ	Contains sufficient for <n> tests</n>	
IVD	For in vitro diagnostic use only	LOT	Lot number	CTRL	Control range	
2°C 30°C	Temperature limitations	444	Manufacturer	REF	Catalog number	
EC REP	Authorized Representative		Use by 6 months from the opening	8	Do not reuse	



Keto-Mojo Europe BV VivaChek Biotech (Hangzhou) Co., Ltd Ground, 1st, 2nd and 3rd floor Level 2, Block 2, 146 East Chaofeng Ro Hangzhou, 311100, China

EC REP Landlink GmbH Emmendingen, Germany Tel / Fax: 0049 7641 962685! E-mail: info@landlink.eu

