



Blood Ketone Test Strips
Package Insert

PRINCIPLE AND INTENDED USE

The **Keto-Mojo™** Blood Ketone Test Strips work with the **Keto-Mojo™ GKI** Multi-function meter as a system to quantitatively measure the Beta-hydroxybutyrate concentration in fresh capillary whole blood from finger and in fresh venous whole blood. Beta-hydroxybutyrate measurement is based on electrochemical biosensor technology using the enzyme of the Beta-hydroxybutyrate dehydrogenase to catalyze a series of enzymic reactions. The current generated from the reactions is proportional to the Beta-hydroxybutyrate concentration in the sample. Via gathering and calibrating the current, the system displays the equivalent of plasma D-3-hydroxyrate values to allow comparison of results with laboratory methods.

The system is intended for self-testing use outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes management. It should not be used for the diagnosis of or screening for diabetes, and not for use on neonates. The system is just for personal use and should not be shared.

COMPOSITION

Each test strip contains the following reactive chemicals: beta-hydroxybutyrate dehydrogenase (HBDH) < 10 IU, Mediator < 100 µg. Each pouch test strip 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 7.5-45°C (45.5-113°F).
- Use the test strips under the humidity of 10% - 90%.
- 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 pouch.
- Do not use your test strips beyond the expiration date (printed on the 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 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 KETONE TEST

Materials provided: **Keto-Mojo™** Blood Ketone Test Strips and package insert. Materials required but not provided: **Keto-Mojo™ GKI** Multi-function Meter, User's Manual, lancing device and a new sterile lancet. Refer to your User's Manual for complete instructions for blood sample collection before use.

1. Wash your hands in with warm water and soap, dry them thoroughly.
2. Prepare the lancing device.
3. Check the expiration date (printed on the pouch). Do not use test strips beyond the expiration date.
4. Insert the test strip into the meter. The meter turns on.
5. Using a lancing device and new lancet 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 ketone test result will appear after the meter counts down from 9 to 1.

EXPECTED CONTROL GOAL

The blood ketone test measures beta-hydroxybutyrate, an important ketone body in the blood.¹ Normally, levels of beta-hydroxybutyrate are expected to be less than 0.6 mmol/L.² Beta-hydroxybutyrate may increase if a person fasts, exercises vigorously or has diabetes and becomes ill.^{1,3} If your blood ketone result is LO and your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, repeat both the ketone and glucose tests with new test strips. If the same result appears again or the result does not match with how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication program. If your blood ketone result is between 0.6 and 1.5 mmol/L and your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's advice. If your blood ketone result is higher than 1.5 mmol/L and your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).²⁻⁶

CHECKING THE SYSTEM

- Use only **Keto-Mojo™** Blood Ketone 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 ketone measurements. Do not use components from other brands.
- Fresh venous 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 65%) and very low (below 20%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- The interference substances listed as follows has been tested and shown no significant effect on **Keto-Mojo™** Blood Ketone Test Strips.

Interference	Concentration (mg/dL)	Interference	Concentration (mg/dL)
Acetacetate	60	Galactose	100
Acetaminophen	15	Gentisic acid	60
Acetone	60	Glucose	450
Acetylsalicylic acid	45	Ibuprofen	30
Ampicillin	3.0	Levo-dopa	4.5
Ascorbic acid	3.0	Maltose	1000
Bilirubin	9.0	Mannitol	1000
Cholestrol	600	Metformin HCl	60
Cholic acid	6.0	Salicylate	45
Creatinine	6.0	Tetracycline	18
D-(-)-Fructose	900	Triglycerides	1000
Dopamine	1.0	Uric acid	20
EDTA	150	Vitamin E	15
Estrone	0.1	Xylitol	1000
Fluoxetine HCl	0.8	Xylose	1000

- The system is tested to accurately read the measurement of ketone in whole blood within the range of 0.1-8.0 mmol/L.
- The **Keto-Mojo™ GKI** Multi-function Monitoring System has been tested and shown to work properly up to 8,700 ft (2,651 meters).
- Severely ill persons should not run the ketone test with the **Keto-Mojo™ GKI** Multi-function Monitoring System.
- 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-Mojo™ GKI** Multi-function meter is calibrated to reflect plasma beta-hydroxybutyrate using Randox assay kit (RB1007).

Repeatability, Precision

Measurement Repeatability Study			
Interval	Beta-hydroxybutyrate Concentration (mmol/L)	Standard Deviation(SD) (mmol/L)	Coefficient of Vavriation(CV)
1	0.397	0.058	--
2	1.391	0.072	--
3	2.543	0.112	4.3%
4	3.435	0.119	3.4%
5	4.910	0.185	3.7%
Intermediate Precision Study			
Interval	Beta-hydroxybutyrate Concentration (mmol/L)	Standard Deviation(SD) (mmol/L)	Coefficient of Vavriation(CV)
1	0.581	0.081	--
2	2.473	0.115	4.5%
3	5.089	0.135	2.7%

System Accuracy

The capillary blood sample and venous blood sample from 100 participants were taken by a trained technician. Capillary blood sample were obtained from fingertip, both capillary blood and venous blood were applied to **Keto-Mojo™ GKI** Multi-function and 3 lots of **Keto-Mojo™** Blood Ketone Test Strips for testing(Y). Venous blood was separated by centrifuging and applied to BioChemical Analyzer to achieve a reference result(X). The results were compared as follow:

Linear Regression Results: Keto-Mojo™ Blood Ketone Test Results vs. BioChemical Analyzer Readings				
Sample Type	Slope	Intercept (mmol/L)	R	N
Capillary Blood from Fingertip	0.9785	0.0080	0.9882	300
Venous Blood	0.9756	0.0010	0.9876	300

Capillary Blood from Fingertip: Keto-Mojo™ Blood Ketone Test Result vs. BioChemical Analyzer Readings			
System Accuracy Results for Ketone Concentration ≥ 1.5 mmol/L			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
29/60(48.3%)	55/60(91.7%)	58/60 (96.7%)	60/60 (100%)
System Accuracy Results for Ketone Concentration < 1.5 mmol/L			
Within ±0.075 mmol/L	Within ±0.15 mmol/L	Within±0.225 mmol/L	Within±0.3 mmol/L
122/240(50.8%)	197/240(82.1%)	236/240(98.3%)	240/240(100%)

Venous Blood: Keto-Mojo™ Blood Ketone Test Result vs. BioChemical Analyzer Readings			
System Accuracy Results for Ketone Concentration ≥ 1.5 mmol/L			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
31/60(51.7%)	50/60(83.3%)	59/60 (98.3%)	60/60 (100%)
System Accuracy Results for Ketone Concentration < 1.5 mmol/L			
Within ±0.075 mmol/L	Within ±0.15 mmol/L	Within±0.225 mmol/L	Within±0.3 mmol/L
113/240(47.1%)	190/240(79.2%)	233/240(97.1%)	240/240(100%)

Venous blood sample were applied to **BIOCHEMICAL ANALYZER** to achieve a reference result. The sample range was from 0.1 to 3.2 mmol/L for **Keto-Mojo™** Blood Ketone Test result of capillary blood and was from 0.1 to 3.2 mmol/L for **Keto-Mojo™** Blood Ketone Test Result of venous blood. 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. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism 1982; 4: 1-27.
2. Wiggam MI, O’Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997; 20:1347-1352.
3. Harano Y, Kosugi K, Hyosu T, Suzuki M, Hidaka H, Kashiwagi A, Uno S, Shigeta Y. Ketone bodies as markers for Type 1 (insulin-dependent) diabetes and their value in the monitoring of diabetes control. Diabetologia 1984; 26: 343-348.
4. Ubukata E. Diurnal variation of blood beta-Ketone bodies in insulin-dependent diabetes mellitus and noninsulin-dependent diabetes mellitus patients: The relationship to serum C-Peptide immuno reactivity and free insulin. Ann Nutr Metab 1990; 34:333-342.
5. Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. Diabetes 1988; 37: 1470-1477.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		Contains sufficient for <n> tests
	For <i>in vitro</i> diagnostic use only		Lot number		Control range
	Temperature limitations		Manufacturer		Catalog number
	Authorized Representative		Use by 6 months from the opening		Do not reuse

Manufactured For:
Keto-Mojo Europe BV
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