



Blood Ketone Test Strips

(Model: VKS01)

Package Insert

PRINCIPLE AND INTENDED USE

The **Keto-Mojo** Blood Ketone Test Strips (VKS01) work with the **Keto-Mojo GK+** Blood Glucose and β -Ketone Meter as a system to quantitatively measure the Beta-hydroxybutyrate concentration in fresh capillary whole blood from finger. 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-hydroxybutyrate values to allow comparison of results with laboratory methods.

The **Keto-Mojo GK+** Blood Glucose and β -Ketone Dual Monitoring System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home, as an aid to monitor the effectiveness of diabetes control. The system is for self-testing, intended to be used by a single person and should not be shared. The **Keto-Mojo GK+** system should not be used for diagnosis of or screening for diabetes and not for use on neonates.

COMPOSITION

Each test strip (VKS01) contains the following reactive chemicals: beta-hydroxybutyrate dehydrogenase (HBDH) < 10 IU, Mediator < 100 μ g. 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.
- Replace the vial cap and close it tightly immediately after removing a test strip.
- Always keep the test strips in the original vial. Use the test strip immediately after removing it from the vial or foil pouch.
- Do not use your test strips beyond the expiry date (printed on the strip vial label or on the foil pouch or on the box) or discard date, whichever comes first, because this may cause incorrect test results.
- Note:** All expiration dates are printed in Year-Month format. 2024-01 indicates January, 2024.
- Write the discard date (6 months after first opening the vial) on the vial label when you first open it. Discard any remaining test strips after the discard date.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test strip 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 GK+** Blood Glucose and β -Ketone 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.

- Wash your hands in with warm water and soap, dry them thoroughly.
- Prepare the lancing device.
- Check the expiration date (printed on the strip vial label or on the foil pouch or on the box). Do not use test strips beyond the expiration date.
- Insert the test strip into the meter. The meter turns on.
- 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 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 (VKC01) as meter and strips. 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 the local distributor for further assistance.

LIMITATIONS

- The **Keto-Mojo GK+** Blood Glucose and β -Ketone Meter, **Keto-Mojo** Test Strips (VKS01) and **Keto-Mojo** Control Solution (VKC01) have been designed, tested and proven to work together effectively to provide accurate blood ketone measurements. Do not use components from other brands.
- Use only with whole blood. Do not use with serum or plasma samples.
- Only fingertip sampling is acceptable.
- 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)
Acetaminophen	15mg/dL	Mannitol	1000 mg/dL
Ascorbic Acid	3 mg/dL	Methyl dopa	10.5 mg/dL
Bilirubin	25 mg/dL	Pralidoxime iodide	2mg/dL
Cholesterol	600 mg/dL	Salicylic acid	45 mg/dL
Creatinine	6 mg/dL	Sodium	350 mg/dL
Dopamine	1 mg/dL	Tolbutamide	100 mg/dL
EDTA	150 mg/dL	Tolazamide	40 mg/dL
Galactose	100 mg/dL	Triglycerides	1000 mg/dL
Genitistic acid	60 mg/dL	Uric acid	20 mg/dL
Glucose	450 mg/dL	Xylose	1000 mg/dL
Glutathione	92.9mg/dL	Sorbitol	1000 mg/dL
haemoglobin	20 mg/dL	Lactose	100 mg/dL
Heparin	8000 IU/dL	Tetracycline	1.5 mg/dL
Ibuprofen	30 mg/dL	Xylitol	500 mg/dL
Icodextrin	2 mg/dL	Lactitol	500 mg/dL
Levo-dopa	4.5mg/dL	Isomalt	500 mg/dL
Maltose	1000 mg/dL	Maltitol	500 mg/dL

- The **Keto-Mojo GK+** 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 GK+** Blood Glucose and β -Ketone Dual Monitoring System has been tested and shown to work properly up to 13,123 ft (4,000 meters).
- Severely ill persons should not run the ketone test with the **Keto-Mojo GK+** Blood Glucose and β -Ketone Dual 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 GK+** Blood Glucose and β -Ketone Meter is calibrated to reflect plasma beta-hydroxybutyrate using Randox assay kit (RB1007).

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 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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
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** for further assistance.

REFERENCES

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- Harano Y, Kosugi K, Hyosu T, Suzuki M, Hidaka H, Kashiwagi A, Uno S, Shigetate 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.
- 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.
- 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
	Use within 6 months of opening		Do not reuse		

Keto-Mojo ULCA
700-401 West Georgia Street
Vancouver BC V6B 5A1