MultiSure GK

Blood Ketone Test Strip

⚠IMPORTANT

PLEASE READ THIS INFORMATION AND YOUR MULTISURE GK USER'S GUIDE BEFORE USING MULTISURE GK BLOOD KETONE TEST STRIP.
For questions and assistance, please contact the authorized representative found at the end of this insert.

Intended Use

The MultiSure GK Blood Ketone Test Strip is to be used with the MultiSure GK meter to quantitatively measure blood ketone in venous whole blood or capillary whole blood. The MultiSure GK Blood Ketone Test Strip is plasma-calibrated for easy comparison to lab results. It is intended for self-testing by people with diabetes or for healthcare professionals use. It is not indicated for the diagnosis or screening of diabetes or for neonate use.

Introduction

The MultiSure GK Blood Ketone Test Strip uses an enzyme to measure blood ketone. When blood touches the tip of the test strip, it flows into the reaction zone. The enzyme reacts with ß-Hydroxybutyrate in blood and produces electrical current. The meter measures the current. The meter shows the test result in 8 seconds.

Reagent Composition

Each cm^2 of test strip contains:

• HBDH	1.5%
• Electron Shuttle	20%
• Non-Reactive Ingredients	78.5%

Warnings and Precautions

The MultiSure GK Blood Ketone Test Strip is for use outside the body (IVD IN VITRO diagnostic use).

- Do not use test strips after the expiration date . Please check the expiration date on the test strip bottle.
- Do not use strips that are wet or damaged.
- Do not reuse the strips.
- ⚠ If you have symptoms that are inconsistent with your test results and you have eliminated common errors as described in the user's guide; contact your healthcare professional immediately.
- Operation temperature for meter and test strip is between 10°C~40°C (50°F~104°F).
- Incorrect results may occur in patients who are dehydrated, severely hypotensive, in shock, or in a hyperglycemic-hyperosmolar state.
- Do not test critically ill patients.
- The MultiSure GK Blood Ketone Test Strip has not been evaluated for alternative site testing (AST).

Storage and Handling

1. Always close the vial cap tightly after removing a test strip. This avoids moisture and direct sunlight.
2. Store the test strips between 4°C ~ 30°C (39°F ~ 86°F). Do not freeze or refrigerate.
3. Store out of direct sunlight.
4. Unopened test strips are stable until the expiration date printed on the bottle when stored properly.
5. The month printed on the label refers to the END of that month.
6. Use within 3 months after first opening.
7. Do not handle the test strips with wet or dirty hands.

Sample Collection and Preparation

The MultiSure GK Blood Ketone Test Strip is designed specifically for use with fresh capillary whole blood taken from a fingertip and venous whole blood drawn from the arm.

- Venous whole blood sample can be collected with EDTA or heparin tubes.
- Plasma and serum samples can not be used.
- Testing must be performed immediately after the sample is obtained.

Test Procedure

See "Testing Your Blood Ketone" in the MultiSure GK User's Guide .

Expected Values

Normally, blood ketone level is expected below 0.6 mmol/L. If level increases, it might represent:

- 0.6 to 1.5 mmol/L- a moderate level of ketone and probably indicates fat metabolism and weight loss, but not a deficiency of insulin, test again later and contact your healthcare professional for advice
- 1.6 to 3.0 mmol/L- a high level of ketone and under a risk of diabetes ketoacidosis (DKA), contact your healthcare professional immediately
- Above 3.0 mmol/L- a serious metabolic condition and emergency medical care is necessary

Consult with your healthcare professional to understand an appropriate blood ketone range for you.

Quality Control

Run Level 1, Level 2 control solution tests. Follow the User's Guide instructions. Do control tests:

- At least once per week to make sure the meter and test strip are working properly.
- If your test strips were stored at temperature and humidity outside proper storage conditions.
- When you use your meter for the first time.
- Every time you open a new bottle of test strips.
- To practice your testing technique.
- If you drop your meter.

Use only MultiSure GK Ketone Control Solution. Your test results should fall within the control range printed on the test strip bottle. Repeat control solution testing if results fall out of range. Results may fall out of range due to:

- Errors in control solution testing
- Expired or contaminated control solution
- Test strip damaged
- Meter malfunction

⚠ If the result continues to fall outside of the printed range, contact the authorized representative found at the end of this insert.

Problem Solving

1.Confirm the test strip is not expired.
2.Make sure the blood fills the reaction zone. "Err 3" will show if there is too little blood. DO NOT add a second drop of blood. Discard the test strip from the meter and retest with a new test strip.
3.Check the system with a control solution test.
4.Refer to "Solving Problems" in the User's Guide for more hints.

Limitations

1.DO NOT use plasma or serum samples.
2.DO NOT test on neonatal (newborn) samples.
3.DO NOT test on arterial samples.
4.Altitudes up to 10335 feet will not affect test results.
5.Hematocrit range: 20~60%.
6.The following substances have no significant effect on blood ketone test results: Acetaminophen (up to 20 mg/dL); Acetone (up to 10 mg/dL); Acetoacetate (up to 10 mg/dL); Ascorbic acid (up to 4 mg/dL); Bilirubin (up to 10 mg/dL); Captopril (up to 10 mg/dL); Cholesterol (up to 500 mg/dL); Creatinine (up to 6 mg/dL); Dopamine (up to 2 mg/dL); Glucose (up to 900 mg/dL); Ibuprofen (up to 50 mg/dL); L-DOPA (up to 3 mg/dL); Methyl-Dopa (up to 7.5 mg/dL); N-acetylcysteine (up to 10 mg/dL); Salicylate (up to 30 mg/dL); Tetracycline (up to 10 mg/dL); Tolazamide (up to 15 mg/dL); Tolbutamide (up to 45 mg/dL); Triglyceride (up to 750 mg/dL); Uric acid (up to 20 mg/dL).

Performance Evaluation Data

Accuracy

A capillary and venous blood comparison study between the MultiSure GK system and STANBIO ß-Hydroxybutyrate LiquiColor® Test Kit yields the following data:

Accuracy for capillary- MultiSure GK

Number of Readings :	600
Sample Range:	0.15 to 7.91 mmol/L

Total within +/-0.3 mmol/L & +/-20%
600/600 (100%)

Accuracy for venous- MultiSure GK

Number of Readings :	600
Sample Range:	0.14 to 7.82 mmol/L

Total within +/-0.3 mmol/L & +/-20%
600/600 (100%)

Precision

3 lots of MultiSure GK Blood Ketone Test Strip were used for within-run repeatability study. Venous blood in heparin-tubes was spiked to 5 concentrations. Blood glucose readings were recorded for 1 day resulting in 300 data points for each concentration; as shown in the following tables:

Precision- MultiSure GK

Number of Readings:	300	300	300	300	300
Mean (mmol/L):	0.5	2.2	3.9	6.1	7.4
S.D. (mmol/L):	0.14	0.10	0.13	0.18	0.19
C.V%:	NA	4.4	3.3	2.9	2.5

Symbols:

- Use-by date
- LOT Batch code
- Temperature limit
- Consult instructions for use
- IVD In vitro diagnostic medical device
- Caution
- REF Catalogue number
- Keep away from sunlight
- Do not reuse
- Manufacturer
- EC REP Authorized Representative in the European community

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Suitable for self-testing

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