

# MultiSure GK

## Blood Glucose Test Strip

### ⚠️ IMPORTANT

PLEASE READ THIS INFORMATION AND YOUR MULTISURE GK USER'S GUIDE BEFORE USING MULTISURE GK BLOOD GLUCOSE TEST STRIP.

For questions and assistance, please contact the authorized representative found at the end of this insert.

### Intended Use

The MultiSure GK Blood Glucose Test Strip is intended to be used with the MultiSure GK Blood Glucose and Ketone Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The MultiSure GK Blood Glucose Test Strip is plasma-calibrated for easy comparison to lab results. It is intended for self-testing by people with diabetes and by healthcare professionals. It is not indicated for the diagnosis or screening of diabetes or for neonate use.

### Introduction

The MultiSure GK Blood Glucose Test Strip uses an enzyme to measure blood glucose. When blood touches the tip of the test strip, it flows into the reaction zone. The enzyme reacts with glucose in blood and produces electrical current. The meter measures the current. The meter shows the test result in 5 seconds.





### Reagent Composition

Each cm<sup>2</sup> of test strip contains:



- GOD 3.5%
- Electron Shuttle 17.5%
- Non- Reactive Ingredients 79%


### Warnings and Precautions

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

- Do not use test strip after their 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 your test result is below 70 mg/dL (3.9 mmol/L) or above 250 mg/dL (13.9 mmol/L), do control solution testing to make sure your system is working properly. Then repeat testing using fingertip blood. If the result is still very high or very low, contact your healthcare professional immediately.
- 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.
- Never make major changes in your diabetes treatment program or ignore symptoms without consulting your physician.
- Operation temperature for meter and test strip is between 5°C~45°C  (41°F~113°F).
- Incorrect results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Do not test critically ill patients with blood glucose meters.
- Incorrect result may occur in individuals who are dehydrated.

### 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.
3. Store out of direct sunlight .

4. Unopened test strips are stable until the expiration date  printed on the bottle when stored properly.
5. Use within 6 months after first opening.
6. Do not handle the test strip with wet or dirty hands.

### Sample Collection and Preparation

Testing must be performed immediately after the sample is obtained.

### Test Procedure

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

### Alternate Site Testing

You can also test from palm and forearm. This is called alternate site testing (AST). AST results may differ from fingertip readings <sup>(1)</sup>.

DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal)
- 2 hours or more after taking insulin
- 2 hours or more after exercise

Alternate Site Testing SHOULD NOT be used when:

- You have hypoglycemic unawareness (not able to tell if you have low blood sugar).
- Within 2 hours of a meal, exercise, or medication.
- You will be operating machinery or driving a car.
- You are sick.
- You think your blood glucose is low.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are pregnant.

Consult your healthcare professional to decide if alternate site testing is right for you.

### Expected Values

Consult with your physician or healthcare professional to determine an appropriate blood glucose target range for you.


### Quality Control

Run Level 1, Level 2 or Level 3 control solution test. Follow the User's Guide instructions. Do control tests:


- If your test results do not agree with how you feel.
- 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 strip.
- To practice your testing technique.
- If you drop your meter.

Use only MultiSure GK Glucose 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
- Damaged test strip
- 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. "Er 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 blood samples.
3. DO NOT test on venous or arterial blood samples.
4. Altitudes up to 10335 feet will not affect test results.
5. Hematocrit range: 10~70%.
6. The following interferences may affect test results.

Interferents	Interference Concentration	Therapeutic Concentration/ Reference Interval
Acetaminophen	>10 mg/dL	1~3 mg/dL
Tolbutamide	>10 mg/dL	5.4~10.8 mg/dL
Ibuprofen	>40 mg/dL	1~7 mg/dL
Acetylsalicylic acid	>40 mg/dL	13~39 mg/dL
Tolazamide	>23 mg/dL	23 mg/dL
Paralidoxime iodide (PAM)	>50 mg/dL	250 mg/dL
Uric Acid	>15 mg/dL	2.5~8 mg/dL
Glutathione	>1.5 mmol/L	0.79~1.05 mmol/L

## Performance Evaluation Data

### Accuracy

A capillary blood comparison study between the MultiSure GK System and YSI 2300 Glucose Analyzer yields the following linear regression data:

Referring to EN ISO 15197:2015	
Number of Readings :	600
Sample Range :	34 to 490 mg/dL 1.9 to 27.2 mmol/L

Accuracy for glucose level <100mg/dL (5.56 mmol/L)			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
107/186	176/186	186/186	
(57.5%)	(94.6%)	(100%)	

Accuracy for glucose level ≥100mg/dL (5.56 mmol/L)			
Within ±5%	Within ±10%	Within ±15%	
291/414	398/414	414/414	
(70.3%)	(96.1%)	(100%)	

Total within ±15mg/dL (0.83 mmol/L) & ±15%	600/600 (100%)
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## Precision

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

Repeatability Study-According to EN ISO 15197:2015						
Number of Readings:	300	300	300	300	300	300
Mean (mg/dL):	41	73	134	219	330	
(mmol/L):	2.3	4.1	7.4	12.2	18.3	
S.D. (mg/dL):	2.6	2.4	3.2	5.6	7.6	
(mmol/L):	0.1	0.1	0.2	0.3	0.4	
C.V%:	NA	NA	2.4	2.5	2.3	












3 lots of MultiSure GK Blood Glucose Test Strip were used for intermediate precision study. 3 levels of control materials were prepared for glucose test and 300 data points were obtained for each level, as shown in the following tables:

Intermediate Precision Study-According to EN ISO 15197:2015				
Number of Readings:	300	300	300	
Average (mg/dL):	41	120	329	
(mmol/L):	2.3	6.7	18.3	
S.D. (mg/dL):	3.0	3.5	6.2	
(mmol/L):	0.2	0.2	0.3	
C.V%:	NA	2.9	1.9	

## User Performance Study

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results: 100% within ± 15 mg/dL (0.83 mmol/L) of the YSI reference values at glucose concentration < 100 mg/dL (5.56 mmol/L) and 100% within ± 15% of the YSI reference values at glucose concentration ≥ 100 mg/dL (5.56 mmol/L).

## Symbols

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

## Traceability

The system is calibrated using reference plasma values determined with a YSI analyzer. The YSI analyzer is calibrated using a series of standards traceable to NIST SRM917C.

## Reference

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708-709, 2005


### CE/REP

Wellkang Tech Consulting  
Suite B 29 Harley Street  
LONDON W1G 9QR  
England, United Kingdom  
Tels: +44(20)32876300/30869438  
Fax: +44(20)76811874  
Email: AuthRep@CE-marking.eu

## ApexBio

**APEX BIOTECHNOLOGY CORP**  
No. 7, Li-Hsin Rd. V, Hsinchu Science Park,  
Hsinchu, Taiwan, R.O.C.  
TEL: 886-3-5641952  
FAX: 886-3-5678302  
E-mail: info@apexbio.com  
Website: www.apexbio.com

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Suitable for self-testing

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