

## Package Insert for Safe AQ UG Blood Glucose Test Strip Suitable for self-testing or professional use

### 【 Product Name 】

Generic name: Blood Glucose Test Strip  
Product Model: Safe AQ UG

### 【 Packing Size 】

5 test strips/box, 10 test strips/box, 25 test strips/box, 50 test strips/box, 100 test strips/box, 150 test strips/box

### 【 Intended Use 】

The Safe AQ UG Blood Glucose Test Strip is intended to be used with the Safe AQ UG Blood Glucose and Uric Acid Meter to quantitatively measure glucose (sugar) in capillary whole blood samples drawn from the fingertips or venous whole blood samples. The Test Strip requires No Coding.

The Safe AQ UG blood glucose test strip, used with Safe AQ UG Blood Glucose and Uric Acid Meter, is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical setting as an aid in monitoring the effectiveness of diabetes control.

The Safe AQ UG blood glucose test strip is intended for use outside the body (in vitro diagnostic use) as an aid to monitor the effectiveness of diabetes control. The Safe AQ UG blood glucose test strip should not be used for the diagnosis of or screening of diabetes.

### 【 Patient Cautions 】

- ▶ For In Vitro Diagnostic Use ( external use only )
- ▶ Please review this sheet and the Safe AQ UG user manual before you use Safe AQ UG Blood Glucose Test Strips. Use Safe AQ UG Blood Glucose Test Strips only with Safe AQ UG Blood Glucose and Uric Acid Meter to get results and you will be accessible to the complete service, support and warranty from Sinocare.
- ▶ The Safe AQ UG Blood Glucose and Uric Acid Meter should not be used on critically patients.

### WARNINGS:

1. Do not use for neonates (newborns or infants).
2. Do not use to screen or diagnose diabetes mellitus.
4. Do not use for critically patients.
5. All parts of the Safe AQ UG kit should be treated as biohazard and can transmit infectious diseases, even after you clean and disinfect.
6. Keep test strip vial away from children. A child could choke on the cap or be harmed if the drying agent in vial is swallowed, inhaled, or contacts skin.

### 【 Test Principle 】

A blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents (special chemicals) on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with the special chemicals and electrons are generated, producing electrical current. The Safe AQ UG meter measures the strength of the electrical current and calculates your blood glucose level.



### 【 Composition 】

The reagent in test strip is composed of FAD glucose dehydrogenase, potassium ferricyanide, buffer solution and stabilizer.etc

### 【 Test Strip Storage and Shelf Life 】

- Shelf life: 24 months if stored between 1°C~30°C.
- Store the test strips at temperatures between 1°C~30°C. Do not freeze.
- Do not store the test strips in high heat and moisture areas such as the bathroom or kitchen.
- Store unused test strips in their original vial with cap closed.

- Close the vial tightly immediately after you take a test strip out.

- Use the test strip immediately after removing it from the container.
- Do not use test strips beyond the expiration (printed on package) or discard date, because it may cause inaccurate results.
- Write the discard date (6 months after first opening the vial) on the vial label when you first open it. Discard remaining test strips after the discard date.
- Do not tamper with the test strip.
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands you may touch the test strips anywhere on its surface.
- Never reuse a test strip that has had either blood or control solution applied to it.
- Never make significant changes in your diabetes treatment program or ignore symptoms without consulting your healthcare provider.

### 【 Test Environment 】

Temperature: 10°C~35°C  
Relative Humidity: ≤80%

### 【 Applicable Meter 】

The Safe AQ UG blood glucose test strip is intended to be used with the Safe AQ UG Blood Glucose and Uric Acid Meter.

### 【 Sample requirements 】

Sample size: 0.6µL  
Test range: 20~600mg/dL (1.1~33.3 mmol/L)  
Test time: 5 seconds.  
Sample type: capillary blood samples or venous whole blood samples. (Please request professional medical staff to apply blood of venous whole blood. The blood sample would be better without anticoagulation, if needed, prepare the blood sample with heparin as the anticoagulation. Test immediately after the blood sample is being applied, otherwise, the test results will be on the low side for the reason of glycolysis.)

### 【 Test Method 】

Getting ready to test  
Refer to the Safe AQ UG Meter User Manual for more detailed information.

1. Required materials: the meter, a test strip, the lancing device and a lancet.
2. Wash hand with warm, soapy water. Rinse and dry completely.

### 【 Performing a blood glucose test 】

Please refer to the Safe AQ UG Meter User Manual for more detailed information.

- Insert a Safe AQ UG Test Strip with the end of contact bar placed into the test strip slot first. The meter turns on.
- Obtain a blood drop using the lancing device.
- Blood will be applied into the Safe AQ UG Test Strip until the reaction chamber is full indicated by a short beep sound.
- If the reaction chamber does not fill completely before the meter begins to count down, do not add more blood to the test strip; discard the test strip and retest.
- After the meter counts down from 5 to 1, it will display test result.

### 【 Reference Value Range 】

Expected blood glucose levels for people without diabetes:

Time	Range, mg/dL
Fasting	Less than 100mg/dL (5.5 mmol/L)

For people with diabetes: Please consult your healthcare professional for the blood glucose range for you own laboratory according to specific region and group. If you

have poor circulation, testing your own blood glucose may not be suitable for you. Ask your healthcare provider. You should treat your low or high blood glucose as recommended by your healthcare provider. With these test strips, your meter displays blood concentrations that refer to plasma although you always apply whole blood to the test strip. For further information please visit our website at [www.sinocare.com](http://www.sinocare.com) or contact your local Sinocare representative.

### 【 Explanation of Test Results 】

**Unusual test results**  
 If “LO” is displayed on your meter, your blood glucose may be below 20 mg/dL (1.1 mmol/L).  
 If “HI” is displayed on your meter, your blood glucose may be over 600 mg/dL (33.3 mmol/L).  
 For detailed information on error code, please refer to your user manual.  
 If your blood glucose result does not match how you feel, follow these steps:

1. Repeat the test with a new test strip.
  2. Perform a control test with Safe AQ UG blood glucose control solution. For detailed information, please refer to your user manual.
  3. Check this list to help you solve the problem.
    - Check the use by date of the test strips.
    - Ensure that the cap on the test strip container is always closed tightly.
    - Ensure that you used the test strip immediately after removing it from the container.
    - Check if the test strips were stored in a cool, dry place.
    - Check if you followed the test steps.
- Please refer to user manual for proper maintenance and handling procedures.
4. If the blood glucose results are too low, too high, or doubtful, please contact your healthcare professional.

### 【 Limitations and considerations 】

- ◆ Please refer to the User Manual for operating temperature and humidity range for the meter.
- ◆ Due to the meter siphon function, sample over size will not affect test results; insufficient sample may lead to incorrect test results.
- ◆ If the test result does not match how you feel, repeat the test and refer to User Manual. If this does not confirm the way you feel, contact your healthcare professional immediately.
- ◆ The test is used for monitoring glucose level of diabetics and cannot be used to diagnose and screen diabetes, neither for testing the glucose relating to any other disturbance of carbohydrate metabolism.
- ◆ Test result will be inaccurate when under special states (dehydration, hyperosmotic state under high blood glucose, hypotension, shock, acidosis and so on).
- ◆ Test result will be inaccurate if hematocrit beyond 30%–60%.
- ◆ Vitamin C, uric acid, acetaminophen and other reducing substance occurring in normal concentration or therapeutic concentrations do not affect test results.
- ◆ Cholesterol below 600 mg/dL, triglyceride below 750 mg/dL, Bilirubin below 25 mg/dL has no effect on blood glucose test results.
- ◆ Do not perform test during or soon after xylose absorption testing. Xylose in the blood will cause false results. Maltose below 200 mg/dL or Galactose below 60 mg/dL do not affect test results.

### 【 Performance Characteristics 】

- ◆ The Safe AQ blood glucose strip complies with the requirements of ISO 15197:2013 ( In vitro diagnostic test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).
- ◆ System measurement range: 20 –600 mg/dL or 1.1–33.3 mmol/L
- ◆ User performance evaluation:

Results for glucose concentrations <100 mg/dL (<5.55mmol/l)		
Within ± 5mg/dL (within ± 0.28mmol/l)	Within ± 10mg/dL (within ± 0.56mmol/l)	Within ± 15mg/dL (within ± 0.83mmol/l)
14/27(51.9%)	26/27(96.3%)	17/27(100%)

Results for glucose concentrations ≥ 100 mg/dL (≥5.55mmol/l)		
Within ± 5%	Within ± 10%	Within ± 15%
37/73(50.7%)	65/73(89.0%)	71/73(97.3%)

### ◆ Accuracy:

Results for glucose concentrations <100 mg/dL (<5.55mmol/l)		
Within ± 5mg/dL (within ± 0.28mmol/l)	Within ± 10mg/dL (within ± 0.56mmol/l)	Within ± 15mg/dL (within ± 0.83mmol/l)
66.3%(127/186)	89.2%(166/186)	97.8%(182/186)
Results for glucose concentrations ≥ 100 mg/dL (≥5.55mmol/l)		
Within ± 5%	Within ± 10%	Within ± 15%
58.0%(240/414)	89.6%(371/414)	97.8%(405/414)

### ◆ Repeatability (n=300):

S1	S2	S3	S4	S5	S6
0.20 mmol/L	0.25 mmol/L	3.6%	3.2%	3.4%	0.7%

### ◆ Intermediate precision (n=300):

S1	S2	S3
-	2.99%	3.47%

### 【 Matters Needing Attention 】

Testing your blood glucose regularly may help you better manage your diabetes.

Since this product comprises small parts that could be swallowed and lead to choking hazard, please keep it away from children.

Please read the package insert before you perform blood glucose testing. If any information in the package insert is difficult to understand, please contact your local Sinocare representative.

For an explanation of symbols used please refer to the end of the insert.

### ↑ References】

- 1 American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care35:S4–S10, 2012.
- 2 D' Orazio et al.: Approved IFCC Recommendation on Reporting Results for Blood Glucose (Abbreviated); Clinical Chemistry 51: 9 1573–1576 (2005).

### 【 Explanation of Symbols 】

Symbol	Title of Symbol
	In vitro diagnostic medical device
	Consult instructions for use
	Temperature limit
	Batch code
	Use-by date
	Do not re-use
	Keep away from sunlight
	Keep dry
	Manufacturer
	Authorized representative in the European Community
	CE Marking and Notified Body Number