

Package Insert for Safe-Accu 2 Blood Glucose Test Strip Suitable for self-testing

[Product Name]

Generic name: Blood Glucose Test Strip
Product Model: Safe-Accu 2

[Packing Size]

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

[Intended Use]

● The Safe-Accu 2 Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) and should not be used for the diagnosis of or screening of diabetes.

● The Safe-Accu 2 Blood Glucose Test Strip is intended to be used with the Safe-Accu 2 Blood Glucose Meter to quantitatively measure glucose (sugar) in capillary whole blood samples drawn from the fingertips or venous whole blood samples.

● The Safe-Accu 2 Blood Glucose Test Strip 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.

WARNINGS:

1. For in vitro diagnostic use only.
2. Do not use for neonates (newborns or infants).
3. Do not use to screen or diagnose diabetes mellitus.
4. Do not use for critically patients.
5. All parts of the Safe-Accu 2 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. Glucose in the sample reacts with the special chemicals and electrons are generated, producing electrical current. The Safe-Accu 2 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 opening date on the vial label when you first open it. Discard remaining test strips after the discard date (6 months after first opening the vial)
- 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-Accu 2 blood glucose test strip is intended to be used with the Safe-Accu 2 meter.

[Sample requirements]

Sample size: 0.6 µL

Test time: 10 seconds.

Sample type: capillary blood samples or venous whole blood samples. (Please request professional medical staff to collect venous whole blood samples. 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 inaccurate because of glycolysis.)

[Test Method]

Getting ready to test

Refer to the Safe-Accu 2 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-Accu 2 User Manual for more detailed information.

● Insert a Safe-Accu 2 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-Accu 2 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 10 to 1, it will display test result.

● Hold meter with test strip pointing down. Press strip eject button to discard test strip into appropriate container.

● **WARNING!** Treat used test strips and lancets as a biological risk. Dispose used test strips and lancets in appropriate container.

[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 suit 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 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 (1.1mmol/L).

If “HI” is displayed on your meter, your blood glucose may be over 600 mg/dL (33.3mmol/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 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.
- ◆ Hematocrit: Your hematocrit (blood count) should be between 30% - 60%. Ask your healthcare professional if you do not know your hematocrit.
- ◆ Test result will be inaccurate when under special states (dehydration, hyperosmotic state under high blood glucose, hypotension, shock, acidosis and so on).
- ◆ Interference: Reducing substances occurring in the blood naturally (uric acid) or from therapeutic treatments (ascorbic acid, acetaminophen, Bilirubin) will not significantly affect results. But abnormal high concentration may affect test results.
- ◆ Lipemic samples: blood concentrations of cholesterol in excess 600 mg/dL or triglyceride concentrations in excess of 750 mg/dL may affect blood glucose results.
- ◆ Xylose: Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.

【 Performance Characteristics 】

- ◆ The Safe-Accu 2 blood glucose monitoring system 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).
- ◆ Detection limit (lowest value display): 20mg/dL (1.1mmol/L)
- ◆ System measurement range: 20-600mg/dL (1.1-33.3mmol/L)
- ◆ Calibration: The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to a NIST standard.
- ◆ 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)
75.7%(109/144)	97.2%(140/144)	100%(144/144)
Results for glucose concentrations ≥ 100 mg/dL (≥ 5.55mmol/L)		
Within ± 5%	Within ± 10%	Within ± 15%
84.0%(383/456)	97.8% (446/456)	100%(456/456)

- ◆ Repeatability: In a typical series of tests, standard deviation (SD) of each concentration level is ≤ 4.58mg/dL when test results are below 100mg/dL (5.55mmol/L) and coefficient of variations (CV) all are ≤ 4.5% when test results are above 100mg/dL (5.55mmol/L).
- Intermediate precision: In a typical series of tests, standard deviation (SD) of each concentration level is ≤ 0.14mg/dL when test results are below 100mg/dL (5.55mmol/L) and coefficient of variations (CV) all are ≤ 4.4% when test results are above 100mg/dL (5.55mmol/L).

【 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 Care 35: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).
3. ISO 15197: 2013, In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

【 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 notify body No.
	Recyclable Waste

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