Package Insert for Safe AQ UG Uric Acid Test Strip
Suitable for self-testing

【Product Name】
Generic name: Uric Acid Test Strip
Product Model: Safe AQ UG

【Packing Size】
10 test strips/vial, 25 test strips/vial, 50 test strips/vial, 100 test strips/vial, 150 test strips/vial

【Intended Use】
The Safe AQ UG uric acid test strip is used only with Safe AQ UG Blood Glucose and Uric Acid Meter to quantitative determine uric acid in human capillary whole blood samples or in the venous samples.
It is intended for use outside the body only (in vitro diagnostic use) for self testing or professional use as an aid in the management of hypeuricemia (HUA).

【Patient Cautions】
► For in vitro diagnostic use only.
► Please read this insert and the meter user manual before test.
► Using other test strips and control solutions with your uric acid meter may produce inaccurate results.
► Not for use on the critically patients.
► Not for neonatal (newborn or infant) use.
► Not for screening or diagnosis of hypeuricemia (HUA).
► Keep the test strip vial away from children. The vial and the test strip can be a choking hazard. Never chew or swallow a test strip.

【Test Principle】
A uric acid test is based on measurement of electrical current caused by the reaction of uric acid with the reagents (special chemicals) on the electrode of the strip. The blood or control solution sample is drawn into the tip of the test strip through capillary action. Uric acid in the sample reacts with the special.
chemicals and generates electrons, which produce an electrical current. The meter measures the electrical current and calculates the uric acid result.

Uric acid+Oxidized Ferrocene Derivative → Allantoin+Reduced Ferrocene+ e−
Reduced Ferrocene+ e− → Oxidized Ferrocene Derivative

【Composition】
The reagent in test strip is composed of ascorbic acid oxidase, ferrocene derivative, buffer solution, etc.

【Test Strip Storage and Shelf Life】
● Shelf life: 12 months if stored between 1℃~30℃
● Store the test strips at temperatures between 1℃~30℃. Keep away from direct sunlight and heat. Do not store in your car. Do not freeze.
● Keep your test strips in the original vial. Do not transfer them to any other vial or container.
● Only remove the test strip from the vial when you are ready to perform a test. Firmly recap the vial immediately after use.
● Do not use the test strips beyond the expiration date printed on the vial.
● Record the discard date on the vial label, which is 3 months from when you first open it. Discard any test strips after 3 months.
● Before handling the test strip, clean your hands with soap and water and dry your hands. You may hold the sides of the test strip when removing it from the vial or inserting it into the uric acid meter.
● Only apply blood to the tip of the test strip. Ensure that the reaction zone is completely filled. Do not place blood on any other part of the test strip. This may cause an inaccurate result.

【Test Environment】
Temperature: 15℃-35℃
Relative Humidity: ≤80%

【Applicable Meter】
The Safe AQ UG uric acid test strip is intended to be used with the Safe AQ UG Blood Glucose and Uric Acid Meter.

【Sample requirements】
Sample size: 3 μ L
Test time: 25 seconds.
Sample type: capillary blood samples or venous whole blood samples.
(Please request healthcare professional 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 meter user manual for more detailed information.
1. Check opened date and printed date next to on test strip vial label. Do not use if after either date printed next to on the test strip vial label or 3 months after date opened, whichever comes first. Discard vial and test with new vial.
2. Allow meter and test strips to sit at room temperature for 30 minutes. If opening vial for the first time, write date opened on vial label.
3. Wash area to be lanced, dry.
4. Coding
coding is uesd to calibrate the meter with the test strips you are using to obtain accurate results. The meter must be coded before using for the first time and every time when you change to another box of test strips.
5. Remove one test strip from vial. Recap vial right away.
6. Insert test strip into test strip port of meter. Meter turns on. Do not remove test strip from meter until testing is finished.
7. Obtain blood drop.
8. With test strip still in meter, touch Sample Tip to top of blood drop and allow blood to be drawn into test strip. Remove test strip from drop immediately after the meter beeps.
9. Result is displayed. Record result.
10. 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】
The Modern clinical laboratory diagnostics-test and clinical (May, 2009, version 2) suggests the reference value range for uric acid are as follow:

Male	202 μmol/L~416 μmol/L(3.4 mg/dL~7.0 mg/dL)
Female	142 μmol/L~339 μmol/L(2.4 mg/dL~5.7 mg/dL)

【Explanation of Test Results】
Unusual test results
If "LO" is displayed on your meter, your Uric Acid may be below 3.0mg/dL(181 μ mol/L).
If "HI" is displayed on your meter, your Uric Acid may be over 20.0mg/dL(1188 μ mol/L).
For detailed information on error code, please refer to your user manual.
If your Uric Acid result does not match how you feel, follow these steps:
1. Repeat Uric Acid test with a new test strip.

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

【Limitations and considerations】
◆ Insufficient sample may cause inaccurate test results.
◆ Hematocrit should between 25% - 55%. Ask your healthcare professional if you do not know your hematocrit.
◆ Normal therapeutic concentrations of ascorbic acid, glucose, creatinine and other reducing substance do not significantly affect results. However, abnormally high concentrations of these substances in blood may cause inaccurately high results.
◆ Lipemic samples: blood concentrations of cholesterol in excess 500 mg/dL(27.8mmol/L) or triglyceride concentrations in excess of 300mg/dL(16.7mmol/L) may affect uric acid results.
◆ Bilirubin excess 6mg/dL(0.3mmol/L) may affect uric acid results.
◆ Acetaminophen excess 1mg/dL(0.05mmol/L) , levodopa excess 0.25mg/dL(0.01mmol/L) may affect uric acid results.
◆ Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
◆ Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may also occur in individuals experiencing a hyperosmo-lar-hyperglycemic- state (HHS).
◆ If you have symptoms that do not reflect your uric acidtest results, and you have followed all instructions described in this owner's manual, call your healthcare professional.

【Performance Characteristics】
System measurement range: 181 μmol/L~1188 μmol/L. (3.0 mg/ dL~20.0 mg/dL)
Calibration: The system is calibrated with venous blood containing various uric acid concentrations. The reference values are obtained using a validated test method.This test method is referenced to the uricase method and is traceable to a NIST standard.
◆ User performance evaluation:

Results for uric acid concentrations < 297 μmol/L (5.0 mg/ dL)		
Within ± 14.9 μmol/L (Within ± 0.3 mg/ dL)	Within ± 29.7 μmol/L (Within ± 0.5 mg/ dL)	Within ± 59.4 μmol/L (Within ± 1.0 mg/ dL)
40.0%(6/15)	60.0% (9/15)	100% (15/15)
Results for uric acid concentrations≥ 297 μmol/L (5.0 mg/ dL)		
Within ± 5%	Within ± 10%	Within ± 15%
57.6%(49/85)	94.1% (80/85)	100%(85/85)

◆ Accuracy:

Test Range	Acceptable Deviation
≤297 μmol/L (≤5.0mg/dL)	within ± 59.4 μmol/L (1.0 mg/dL)
>297 μmol/L (>5.0mg/dL)	within ± 20%

Repeatability: In a typical series of tests, standard deviation(SD) of each concentration level is ≤10.7 μmol/L (0.2 mg/ dL) when test results are below 297 μmol/L (5.0 mg/ dL)and coefficient of variations(CV) all are ≤3.6% when test results are above 297 μmol/L (5.0 mg/ dL)
Intermediate precision: In a typical series of tests, standard deviation (SD) of each concentration level is ≤10.5 μmol/L (0.2 mg/ dL) when test results are below 297 μmol/L (5.0 mg/ dL)and coefficient of variations(CV) all are ≤ 3.8% when test results are above 297 μmol/L (5.0 mg/ dL)

【Matters Needing Attention】
Testing your uric acid regularly may help you better manage your hypeuricemia (HUA).
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 uric acid 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】
The Modern clinical laboratory diagnostics-test and clinical (May, 2009, version 2)

【Explanation of Symbols】

Symbol	Title of Symbol
IVD	In vitro diagnostic medical device
	Consult instructions for use
	Temperature limit
LOT	Batch code
	Use-by date
	Do not re-use
	Keep away from sunlight
	Keep dry
	Manufacturer
EC REP	Authorized representative in the European Community
CE 0123	CE Marking and Notified Body Number