isaw®

Uric Acid Test Strips
UA01

CE 0197 IVD 2℃ 30℃

For self-testing and in vitro diagnostic use only.

IMPORTANT
Read this package insert and the user's manual of the ***isaw***® Multi-Monitoring Meter before testing your uric acid with these Uric Acid Test Strips. The user's manual contains all the information you need to perform a uric acid test.

INTENDED USE
isaw® Uric Acid Test Strips are used with the ***isaw***® Multi-Monitoring Meter for quantitatively measuring uric acid in fresh capillary whole blood or Venous blood. ***isaw***® Uric Acid Test Strips are intended for self-testing outside the body (in vitro diagnostic use) by people at home and health care professionals in the clinical setting.

STORAGE AND HANDLING
- Store the test strips package in 2°C-30°C. Keep away from direct sunlight and heat. Do not refrigerate.
- Store your test strips in their original vial only; do not transfer them to a new vial or any other container.
- After removing a ***isaw***® Uric Acid Test Strip from the vial, immediately replace the vial cap and close it tightly.
- Use each test strip immediately after removing it from the vial.
- Write the date opened on the vial label. Discard remaining ***isaw***® Uric Acid Test Strips 3 months after first opening the vial.
- Avoid getting dirt or food on the test strip.
- Do not use Uric Acid Test Strips beyond the expiration date printed on the package since they may cause inaccurate results.
- Do not bend, cut or alter a ***isaw***® Uric Acid Test Strips in any way.
- Use universal blood precautions when handling and disposing of uric acid monitoring materials. All patient samples are materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection. Follow proper precautions in accordance with local regulations when disposing of all materials.

WARNING: Keep the test strip vial away from children; the cap is a choking hazard. Also, the vial or cap may contain drying agent that are harmful if inhaled or swallowed and may cause skin or eye irritation.

PRECAUTIONS TO OBTAIN ACCURATE RESULTS
- Code the ***isaw***® Brand Meter to match the code number printed on the ***isaw***® Uric Acid Test Strips vial.

- Use only ***isaw***® UA01 Uric Acid Test Strips with ***isaw***® LBM-01 Multi-Monitoring Meter to obtain accurate and consistent blood uric acid results.
- If you are experiencing symptoms that are not consistent with your blood uric acid test results AND you have followed all instructions described in your ***isaw***® Multi-Monitoring Meter User's Manual.
- Never make significant changes to your uric acid control program or ignore physical symptoms without speaking with your healthcare professional.

TEST PROCEDURE FOR BLOOD URIC ACID MEASUREMENT
Materials provided: ***isaw***® Uric Acid Test Strips.
Materials required but not provided: ***isaw***® Multi-Monitoring Meter with User's Manual; Adjustable Lancing Device, New Sterile Lancet.

BLOOD SAMPLE COLLECTION
To obtain a drop of blood, follow these steps.
Step 1: You may obtain a blood drop from a fingertip. Wash your hands with warm, soapy water. Dry them thoroughly.

Step 2: Lance the fingertip. Hold the sampler firmly against the side of your finger. Press the release button. Massage the fingertip to obtain a round drop of blood. Do not squeeze the puncture site excessively. The blood sample should be at least 1.5μL in volume or you may get an inaccurate result.

BLOOD URIC ACID TESTING
Step 1: Insert a test strip. Remove a test strip from the vial. Recap the vial immediately. Insert a test strip, contact bars end first and facing up, into the test port. Push it in until it will go no further. The meter will turn on and the display check will appear briefly. Then the code number will appear, followed by the ▲ symbol. Be sure the meter and test strip codes match. IF they do not, code the meter correctly.

Step 2: Apply sample. Using the adjustable blood sampler, obtain a blood sample large enough to fill the confirmation window. When the ▲ symbol appears on the display, touch and hold the drop of blood to the narrow channel in the top edge of the strip.

DO NOT:
- Apply sample to the front and back of the test strip.
- Push your finger against the test strip.
- Apply a smeared sample.

Hold the blood drop to the top edge of the test strip until the confirmation window is full before the meter begins to count down. If the confirmation window does not fill completely before the meter begins to count down, do not add more blood to the test strip; discard the strip and retest. If the confirmation window is not full you may get an Er5 message or an inaccurate test result.

Step 3: Get accurate results in just 5 seconds. Your blood uric acid result will appear after the meter counts down from 5 to 0. Blood uric acid test results are automatically stored in the meter memory. Turn the meter off by removing the test strip.For detailed information on the test procedure and coding your meter, please refer to your ***isaw***® Multi-Monitoring Meter User's Manual.

TEST RESULTS
isaw® Multi-Monitoring Meter displays uric acid results between 90 and 1190μmol/L (1.5-20 mg/dL). If your test result is lower than 90 μmol/L(1.5mg/dL), "Lo" will appear on the meter display. This indicates severe low blood uric acid. If your test result is above 1190μmol/L(20mg/dL), "HI" will appear on the meter display. This indicates severe high blood uric acid. You should seek immediate medical assistance.

RANGE OF EXPECTED VALUES
Blood uric acid management requires the help of a health care professional. Together you can set your own range of expected blood uric acid value, arrange your testing times, and discuss the meaning of your blood uric acid results. Expected blood uric acid levels for people is: men 149-416μmol/L(2.5-6.9mg/dL), women 90-357 μmol/L(1.5-5.95mg/dL).

If You Get Unexpected Results
IMPORTANT: Low or high blood uric acid readings can indicate a potentially serious medical condition. If your blood uric acid reading is unusually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood uric acid results is less than 90μmol/L (1.5mg/dL) or higher than 416μmol/L (6.9mg/dL), you should contact your healthcare professional and follow his or her treatment advice.

QUALITY CONTROL: CHECKING THE SYSTEM
Do a Control Solution Test:
- When you begin using a new vial of Uric Acid Test Strips
- When your blood uric acid test results are not consistent with how you feel, or when you think your results are not accurate
- At least once a week
- Whenever you suspect that the meter or Uric Acid Test Strips are not working properly
- If you drop the meter

When control solution is applied to the top edge of ***isaw***® Uric Acid Test Strips, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:
- Error in performing the test
- Test strip deterioration
- Failure to shake the control solution vial well enough (must shake vigorously）
- Meter malfunction
- Control solution is too warm or too cool
- Expired or contaminated control solution
- Failure to discard the first drop of control solution
- Improper coding of the meter

IMPORTANT: If you continue to get ***isaw***® Control Solution test results that fall outside the range printed on the vial, the ***isaw***® Multi-Monitoring Meter may not be functioning properly. Do not use the meter to test your blood uric acid until you get a control solution test result that falls within the range.

LIMITATIONS

isaw® Test strips give accurate results when the following limitations are observed:

- The Uric Acid Test Strips should not be used for the testing of newborns.
- The Uric Acid Test Strips are for single use only. Do not reuse.
- The Uric Acid Test Strips are specific to uric acid and do not react to other things which may be present in blood.
- Use only fresh capillary whole blood. Do not use serum or plasma.
- Extremes in haematocrit may affect test results. Haematocrit levels less than 30% may cause falsely high readings and haematocrit levels greater than 55% may cause falsely low readings. If you do not know your haematocrit level, consult your healthcare professional.
- In-vitro Diagnosis.

Healthcare professionals-please note these additional limitations:

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within 10 minutes. Do not use other anticoagulants or preservatives.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substance (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Patients undergoing oxygen therapy may yield falsely lower results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis). Critically ill patients should not be tested by ***isaw***® Multi-Monitoring Meter.

TEST PRINCIPLE

Uric Acid in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the ***isaw***® Multi-Monitoring Meter and displayed as your blood uric acid results. The strength of these current changes with the amount of uric acid in the blood sample.

REAGENT COMPOSITION

Each Test Strip contains potassium ferricyanide: 1.2-2.0 mg; otheringredients (buffer, etc.): 0.16-0.23 mg. The vial contains a drying agent.

PERFORMANCE CHARACTERISTICS

The performance of ***isaw***® Uric Acid Test Strips has been evaluated both in laboratory and in clinical tests.

Accurancy: the accurancy of ***isaw***® Uric Acid Test Strips and ***isaw***® Multi-Monitoring Meter was assessed by comparing uric acid results obtained using a reference method. The following results were obtained by 110 patients.

Table 1 Regression Analyses

slope	0.9647
y-intercept	12.411 μmol/L
correlation coefficient	0.9749
no.of samples	110
range tested	87-1233 μmol/L

Figure 1 Regression Plot

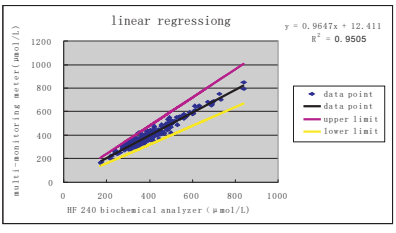

Table 2 System Accuracy Results for Uric Acid Concentration＜5.00mg/dL(300μmol/l)

Within±20μmol/L (±0.33mg/dL)	Within±40μmol/L (±0.67mg/dL)	Within±60μmol/L (±1.0mg/dL)
59/99 （59.6%）	86/99(86.9%)	97/99(98.0%)

Table 3 System Accuracy Results for Uric Acid Concentration ≥5.00mg/dL (300μmol/L)

Within ±5%	Within±10%	Within ±15%	Within±20%
332/561(59.2%)	479/561(85.4%)	517/561(92.2%)	546/561(97.3%)

Table 4 System Accuracy Results for Uric Acid Concentration Between 1.45 mg/dL (87μmol/L) and 20.55mg/dL (1233μmol/L)

Within ±1.00mg/dL or ±20% (Within ±60μmol/L or ±20%)
643/660(97.4%)

This study shows that the system compared well with a laboratory method.

Precision:

Table 5 Measurement Repeatability

	biochemical analyzer average value (μmol/L)	Meter test average value (μmol/L)	Meter test standard deviation	Meter test variable coefficient
sample 1	217	242	13.83	5.71%
sample 2	324	342	15.99	4.68%
sample 3	528	544	21.43	3.94%
sample 4	791	780	26.87	3.44%

This study shows a variability from strip to strip in blood tests of 5.81% or less.

User performance evaluation

A study evaluating uric acid values from fingertip capillary blood samples obtained by 110 lay persons showed the following results: 100% within ±60 μmol/L (±1 mg/dL) of the medical laboratory values at uric acid concentrations below 300 μmol/L (5.0 mg/dL), and 98.8% within ±20 % of the medical laboratory values at uric acid concentrations at or above 300 μmol/L (5.0 mg/dL).

Measurement range: The measurement range of ***isaw***® Multi-Monitoring Meter is 90 to 1190μmol/L (1.5-20mg/dL).

Notes on Symbols and Marks

STRIP	Uric Acid Test Strips
	Consult instructions for use
	Caution
IVD	In vitro diagnostic medical device
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Contains sufficient for < n > tests
	Manufacturer
	Date of manufacture
REF	Catalogue number
LOT	Batch code
	Use-by date
CE 0197	Conformity with Directive 98/79/EC
EC REP	Authorized representative in the European Community / European Union

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