Lumigenex

CE

Instructions for use

Uric acid Test Strips (Dry chemical method)

Product name

Product name: Uric acid Test Strips (Dry chemical method)

Packing specifications

Aluminum foil bag packaging: 15 test /box; 50 tests/box。

Cylinder package: 50 tests/kit (25 tests/cylinder×2 cylinders).

Intended Use

The Uric acid Test Strips (Dry chemical method) by dry chemistry analyzer, suitable for in vitro quantitative detecting the concentrations of uric acid in whole blood or serum samples.

Uric acid is the main products of decomposition of purine metabolism in human body. Most uric acid is formed in the liver and is excreted by the kidneys, determined by the balance between the synthesis and excretion of uric acid in the body. Hyperuricemia can be primary hyperuricemia and secondary hyperuricemia, including excess production or reduced excretion. Quantitative determination of uric acid excretion can help to determine the treatment regimen for hyperuricemia, and to determine whether patients should be treated with uric acid stimulating excretion drugs for increased renal excretion, or treated with allopurinol to inhibit purine synthesis. At present, the commonly used methods to detect uric acid in blood samples include uricase colorimetric method, urine enzyme electrode method, dry chemical method and tungsten-molybdophosphate method.

Test Principles

The whole blood or serum samples to be tested are added dropwise to the uric acid test card. The test substance in the sample reacts with the substance on the test card and produces a color. The depth of the color is related to the concentration of the test substance. The dry chemical analyzer collects the intensity of the reflected light and uses the reflection coefficient to calculate the uric acid concentration in the sample.

$$\text{Uric acid} + H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2$$

$$H_2O_2 + \text{4-Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Iminoquinone} + 4H_2O$$

Main Components

1. The test card is composed of a stuck shell and a test strip. The test strip consists of a diffusion membrane, a blood filter membrane, an auxiliary blood filter membrane, and a reaction membrane (containing various enzyme substances: uricase content is about 0.15U; Peroxidase has 1.2U; 4- aminoantiimidoline (ca. 100μg).
2. One IC card/box contains specific batch number test card information.
3. One copy of instructions per box.
4. Traceability: Biochemical analyzer: Beckman AU680, kit: Beckman uric acid determination kit (uricase-peroxidase method)

※ Do not cross use products with different lot Numbers.

Storage Conditions and Expiry Date

For Aluminum foil bag package: unopened reagent kits are stable at 4°C ~30°C for 18 months tentatively. Please use the test strip within 1 hour once the foil bag is open.

For cylinder package: unopened reagent kits are stable at 4°C ~30°C for 18 months tentatively.the test strips in cylinder are stable at 4°C ~30°C for 30 days tentatively once the cylinder package is opened.

Compatible Equipment

Use the kit with Dry Chemical Analyzer（manufactured by Lumigenex): LP-100, Total F, Total M, Total P

Specimen Collection and Handling

1. Suitable for whole blood and serum samples.
2. Whole blood sample collection: Use heparin anticoagulation tube (or use EDTA anticoagulation tube) for blood collection, or add anticoagulant to the blood collection tube first, add the collected blood sample and shake it for use. The blood sample collection should be used as soon as possible, if the blood can not be detected within 2 hours, they should be stored in a refrigerator at 2-8℃ for no more than 8 hours.
3. After the whole blood sample collected in anticoagulant-free, to be detected as soon as possible.
4. There may be deviations in the test results of hemolysis and turbid samples, so it is not recommended.
5. Serum samples were collected: serum should be separated as soon as possible after blood, in order to avoid hemolysis. The separated serum should be tested as soon as possible. If it cannot be tested within 4 hours at room temperature, it should be stored at 2-8°C for 7 days; it can be stored frozen below -18°C for 3 months (low temperature storage or transportation) The specimen should be equilibrated to room temperature before testing, and inverted to mix).

Directions For Testing

1. Please read the operation manual carefully before testing.
2. Check and insert IC card into the instrument to ensure that the test card matches the batch number of IC card.
3. Take out the test card from the original packaging aluminum foil bag, with the white paper card facing up, insert it into the analyzer, and insert it to the end until it cannot go any further.
4. When the words "add sample" appear on the display screen, drop a 20 μL sample into the sample well.
5. Test results appear on the screen in about 4 minutes. The operation of the instrument shall refer to the application of reagent test in the user manual of The dry chemistry-analyzer of Lumigenex Company.
6. Calibrator and quality control instructions: The test strip adopts IC card calibration mode, and the analyzer automatically reads batch-specific calibration data from the IC card without user calibration.
7. Take out and discard the test card, which is disposable and cannot be used again.

Reference interval

Detect the samples of 160 healthy people of different genders and ages without related diseases is detected. Select the 95% distribution range of these 160 samples to determine the reference interval:

1. Male: 208μmol/L ~428μmol/L (3.5mg/dL~7.2mg/dL)
2. Female: 155μmol/L ~357μmol/L (2.6mg/dL~6mg/dL)

Due to differences in geography, race, gender, etc., it is recommended that each laboratory establish own reference interval.

Interpretation of test Results

1. The instrument will automatically calculate the test results and display them on the screen in mol/L by default.
2. Results below the range show "<120μmol/L " (less than). The out-of-range result shows ">1200μmol/L" (more than).
3. Important: "<120μmol/L" (less than), ">1200μmol/L" (more than) test results or unexpected results, the article with a new unused detection test again.

Limitations

1. The testing results of this kit is only for clinical reference, test results need to combine history and other clinical findings and diagnosis. If the test results do not match clinically, further examination is required.
2. The test strip showed no significant interference at the following concentrations of interfering substances: Hemoglobin≤145g/L, bilirubin≤8mg/dL, lipids≤2g/L, ascorbic acid≤10mg/L
3.The hematocrit: sample hematocrit value in the range of 30% to 45% will not interfere with the test results.

Product Performance

1. Appearance: A) Each component of the kit should be complete;
   B) Packaging labels should be clear and easy to identify;
2. Width of internal strip: ≥9.5mm;
3. Linear range: Within the range of 120μmol/L ~1200μmol/L, linear correlation coefficient R ≥0.9500;
4. Accuracy: Within the detection range, the relative accuracy deviation of UA should be ≤±15%;
5. Repeatability: Coefficient of variation CV (%) ≤15%;
6. The LoD: no higher than 60μmol/L;
7. Inter-batch difference: Coefficient of variation CV (%) ≤15%

[Date of production and term of use] See the product label for details

Warnings and Precautions

1. For medical professional in vitro diagnostic use only.
2. The detection temperature is 20~30°C.
3. It is forbidden to use test strips that do not match the lot number of the IC card.
4. The sample and test strips should be balanced to 20~30°C before testing. After the test strip is taken out of the aluminum foil bag or drying cylinder, it should be used as soon as possible to avoid leaving it in the air for too long, which may lead to inaccurate test results.
5. There may be deviations in the test results of hemolytic and turbid samples, therefore it is not recommended to use.
6. Do not use expired test strips.
7. All samples should be added onto the test strip all at once. If not, do not add the sample again. Retest a new test strip with fresh sample.
8. The test strip can only be tested once. Never insert or read used test cards.
9. Dispose of all specimens and materials resulted from the test as biohazardous waste.
10. Store in a cool and dry place. The wet environment will affect the test results.
11. Please close the cylinder cap tightly and timely after opening the cap to take the test strip.

References

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4. Kutzing M K, Firestein B L.Altered uric acid levels and disease states[J].J Pharmacol Exp Ther, 2008, 324(1):1-7.
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Symbols

	Consult Instructions for Use	LOT	Batch Code
	Do not reuse		Manufacturer
IVD	In-vitro diagnostic device		Do not use if package damaged
4°C 30°C	Temperature limitation		Expiry date
EC REP	European Representative		Fragile. Handle with care
	Set up		Protect from moisture
	Avoid direct sunlight		Date of manufacture

Manufacturer
Lumigenex (Suzhou) Co., Ltd.
Address: Building C24, 218 Xing Hu Street, SIP, Suzhou, P.R. China 215123
Tel: +86 512-80988088
E-mail: lumi@lumigenex.com

European Representative
Riomavix S.L.
Address: Calle de Almansa 55, 1D, Madrid 28039 Spain,
Tel.: +34 658 396 230, E-mail: leis@riomavix.com

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