This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Notification No. 21600AMZ00493000

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This package insert must be read carefully prior to use.

Uric acid assay kit
(Classification No.: 30183002)

QUALIGENT UA

General Precautions **

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the "2. Interfering Substances," in the "Procedural Precautions" section, as well as "2. Precautions for Assessment" in the "Assessment of Assay Results" section, of this package insert.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
UA Enzyme Solution 1:
N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine sodium
UA Enzyme Solution 2:
Uricase
4-Aminoantipyrine

Intended Use

Measurement of uric acid in serum, plasma, or urine

Uric acid is a metabolite of purines, and hyperuricemia causes gout. It is also known that the uric acid concentration increases when renal excretion is impaired.

Assay Principle

1. Assay Principle

Uric acid is oxidized by uricase to produce hydrogen peroxide. Hydrogen peroxide causes oxidative condensation of 4-aminoantipyrine and N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine (TOOS) to form a complex with a red-purple color. The uric acid content is determined by measuring the absorbance of this complex. The influence of ascorbic acid in samples is blocked by ascorbate oxidase.

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + H_2O_2 + CO_2$$

$$H_2O_2 + \text{TOOS} + \text{4-Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Red-purple color}$$

2. Features

1) Wide assay range.
2) Bilirubin, hemolysis and ascorbic acid have minimal effects on results.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum, plasma (heparin plasma, EDTA plasma, citrated plasma and NaF-EDTA plasma) or urine may be used.
2) Storage of samples
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows[5]:
2–10°C: for tests within 5 days
≤ -20°C: for tests after more than 5 days
Bring samples to room temperature (15–30°C) before use.
Urine samples should be tested on the same day.

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), ascorbic acid (up to 50 mg/dL), or formazin turbidity (up to 3000 FTU).
2) When samples from patients with hyperglobulinemia are measured, turbidity may occur and abnormal values may be obtained after addition of the first reagent.
3) When samples from patients receiving uric acid degrading enzyme preparations for cancer chemotherapy are measured, the uric acid level obtained may be lower than the actual level.

3. Others

1) Always use Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum UA-E Standard Solution for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

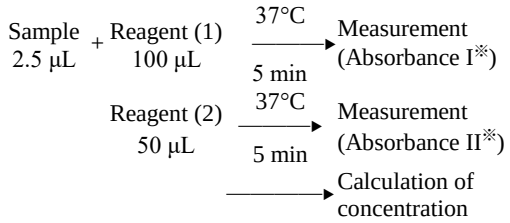
1. Preparation of reagents

Reagent (1): UA Enzyme Solution 1 is ready to use.

Reagent (2): UA Enzyme Solution 2is ready to use.

2. Assay Procedure

This product is compatible with Hitachi 9000 series and LABOSPECT series automated analyzers. Assay procedure is indicated below.



※ Absorbance I and II: The difference in absorbance between 800 nm and 600 nm.
Calibration material: Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum UA-E Standard Solution (Manufacture's assigned value)
Reagent blank: Purified water or saline.

Assessment of Assay Results **

1. Reference standard range

In blood[6]: male, 3.7–7.8 mg/dL
female, 2.6–5.5 mg/dL
In urine[7]: 0.4–1.2 g/day

2. Precautions for Assessment

There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance

1. Sensitivity

1) Reagent blank: absorbance being equal to or lower than 0.05
2) Sensitivity: The absorbance is 0.26–0.39 per 20 mg/dL of uric acid.

2. Accuracy: 90–110% of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation ≤ 3%
(Test methods used for 1.–3.are in-house methods.)

4. Measurement Range[8]: (On a Hitachi 9000 series automated analyzer)

0.2–100 mg/dL

5. Correlation[8]

1) Serum N=100 r=0.999 y=0.99x–0.13
Control method: Approved in vitro diagnostic s (enzymatic method)
2) Plasma N=140 r=0.999 y=1.00x –0.04
Control method: Approved in vitro diagnostics (enzymatic method)
3) Urine N=50 r=0.999 y=0.98x –0.13
Control method: Approved in vitro diagnostics (enzymatic method)

6. Standard Material

SRM913 (NIST)

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) ProClin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the UA Enzyme Solution 1. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.
3) Sodium azide is added as an antiseptic agent in the UA Enzyme Solution 2. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.
5) Sodium azide has been added as an antisepticagent in the UA Enzyme Solution 2. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions

1) Do not use the containers for other purposes.
2) Do not take apart the reagent cartridge before.

Storage and Shelf Life *

1. Storage temperature: 2–10°C

2. Shelf life: 1year from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging *

Name	Package		
QUALIGENT UA	Set (Cassette for Hitachi 9000 series)	UA Enzyme Solution 1 1 × 15.0 mL	× 2
		UA Enzyme Solution 2 1 × 7.5 mL	
	L set (Set for Hitachi LABOSPECT series)	UA Enzyme Solution 1 1 × 40 mL	× 2
		UA Enzyme Solution 2 1 × 20 mL	

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References **

1) Gochman, N., et al. Clin. Chem, 17, 1154, 1971.
2) Meites, S., et al. Clin. Chem, 19, 675, 1973.
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4) Sakamoto S. Med Tech, 26, 7, 783. 1998. Japanese.
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6) Kanai M. (supervising editor). Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
7) Kanai M. (supervising editor). Kanai's manual of clinical laboratory medicine. 34th ed. Tokyo: Kanehara Shuppan; 2015. Japanese.
8) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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