Uric Acid Assay Kit (UA)

Method: Enzymatic

Cat .No.	Size	Instrument
GB320S	R1: 2×80 ml R2: 1×40 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS321S	R1: 2×70 ml R2: 1×35 ml	For Hitachi 917 & OlympusAU640/400/600
GH321S	R1: 2×50 ml R2: 1×25 ml	For Hitachi 902
GX321S	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9 /LX20/DXC600-800
GT321S	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA 40

INTENDED USE

For the *in vitro* quantitative determination of Uric Acid in serum .

CLINICAL SIGNIFICANCE[1,2]

Uric acid is end product of the purine metabolism. In gout, the most common complication of hyperuricemia, increased serum levels of uric acid lead to formation of monosodium urate crystals around the joints. Further causes of elevated blood concentrations of uric acid are renal diseases with decreased excretion of waste products, starvation, drug abuse and increased alcohol consume as well as use of certain medicaments. High uric acid levels also constitute a indirect risk factor for coronary heart disease. Hypouricemia is seldom observed and associated with rare hereditary metabolic disorders.

ASSAY PRINCIPLE[3]

Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with TBHBA and 4-aminoantipyrine to a quinone dye. The absorption of the solution of this dye is proportional to the concentration of uric acid in the sample.

$$\text{Uric acid} + H_2O + O_2 \xrightarrow{\text{uricase}} \text{allantoin} + CO_2 + H_2O_2$$

$$\text{TBHBA} + \text{4-AAP} + 2H_2O_2 \xrightarrow{\text{POD}} 2H_2O + \text{quinone dye}$$

SAMPLE COLLECTION AND PREPARATION

Serum samples.
Serum samples are stable for 3 days at room temperature, or for 6 months at -20°C.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1	
Phosphate buffer PH=7.0	100 mmol/L
Peroxidase	1mmol/L
Reagent 2	
Phosphate buffer PH=7.0	100 mmol/L
4-AAP	0.3 mmol/L
$K_4[Fe(CN)_6]$	10 μmol
POD	>2 KU/L
Uricase	> 30 KU/L

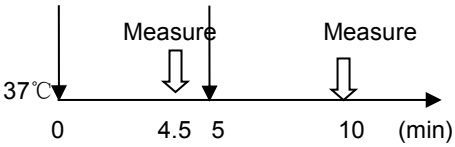
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagents are stable for 1 month after opening and kept at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: 2 Point End 16-34
Wave Length (main/sub): 546 nm/660 nm

Sample:4μl
R1: 200 μl R2: 50 μl



1. Mix 4 μl sample with 200 μl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1 .
2. Add 50 μl R2 into cuvette, mix and incubate for 5 minutes at 37℃, Read final absorbance A_2 .
3. Calculate the absorbance change $\Delta A = A_2 - A_1$.

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample} - \Delta A_{blank}}{\Delta A_{calibrator} - \Delta A_{blank}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least

once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

REFERENCE VALUE

Men: 3.4 -7.0 mg/dl (200-420 μmol/dl)
Women: 2.4 -5.7 mg/dl (140-340 μmol/dl)
It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

CONVERSION FACTORS

mg/dl ×59.4= μmol/L

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CE Revised 01DEC11 version 0801

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 1190 µmol/L. If the samples above this concentration should be diluted 1+1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

PRECISION
The CV of the test should be CV% ≤ 5%

Inter assay precision		
N=5	Level1	Level 2
Mean	358.93	559.13
SD	2.89	5.08
Cv	0.81%	0.85%
Intra assay precision		
N=20	Level1	Level 2
Mean	341	558.6
SD	1.81	2.29
Cv	0.53%	0.41%

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:
Hemoglobin: 200 mg/dl
Intralipid: 3000 mg/dl
Bilirubin: 10 mg/dl

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=0.992X+1.337, R^2=0.998

SAFETY PRECAUTIONS AND WARNINGS
1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagent contains sodium azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Barham, D., and Trinder, P., Analyst 97, 142-145 (1972)
2. Fossati, P., Prencipe, L., and Berti, G., Clin. Chem. 26/2, 227-231 (1980)
3. Thefeld, W. et al. Dtsch. Med. Wschr. (1973) 98, 380.
4. Krieg, M. et al. J. Clin. Chem. Clin. Biochem.(1986) 24, 863.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
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