Uric Acid (UA)
(Enzymatic/Uricase-POD Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **UA0011**	R.1: 3 x 50 ml R.2: 3 x 50 total 300 ml	2-8°C
Cat. No.: **UA0017**	R.1: 3 x 50 ml R.2: 3 x 50 total 300 ml	2-8°C

- **Intended Use:**
In Vitro Diagnostic reagent pack for the quantitative determination of Uric Acid in human serum/plasma and urine on automated and semi-automated photometric systems.

- **Summary and Explanation:**
The Uric Acid is a final product of purine metabolism. In Gout the high concentration of Uric acid in serum generate a crystal complex termed mono sodium urate which precipitate in joints and painful. The other side effect of high Uric acid is kidney failure and indirect cause high risk in heart disease.
The Hyperuricemia, rarely appear in genetic disorder.
Several factors such as kidney disease, failure in filtration, alcohol, starvation and consume some medication can increase the quantitative of uric acid. Therefore, measurement of uric acid to evaluate the function of kidney, gout and leukemia is essential as this factor increase the ratio of production and apoptosis in cells.
The high amount of uric acid is very common due to kidney failure in hospitalization patient compare to gout. This assay is very essential for estimate the pre attention of eclampsia. Meanwhile, the level of uric acid in the blood reflect the liver damage in pregnant toxicity.
The high level of uric acid observed in some cases such as alcoholism, arthrosis, atherosclerosis, heavy exercise, fasting, graves' disease, leukemia, gout, kidney disease and dehydration.
The clinical significant of evaluate the level of uric acid is vital because of low solubility of this molecule in human body.

Principle of the Method:
This method is based on oxidation of uric acid by uricase which all interference chemical materials are erased. The hydrogen peroxide produced in the present of peroxidase and 4-aminoantipyrine a color complex performs. The intensity of color is directly related to amount of uric acid in the sample which measuring at 520 nm.

$$\text{Uric Acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoine} + CO_2 + H_2O_2$$
$$\text{DCPS} + \text{4-Aminoantipyrine} + 2H_2O_2 \xrightarrow{\text{POD}} \text{Quinoneimine} + 3H_2O$$

- **Reagent Preparation and Stability:**
Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date. If in this assay want to work with single reference so the ratio of mixture should be 1 parts from R1 and 1 part of R2.
The stability at 2-8°C for 7 days at 15-25°C for 4 days.
Do not freeze and protect from light.
R1 is transparent and colorless.
R2 transparent and light yellow color.

Waste Management:
Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**
For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**
Use fresh serum, non-hemolysis, plasma heparinized or EDTA and urine. The stability of Uric Acid in the serum/plasma samples at 20-25°C in 3 days, at 2-8°C in 7 days and -20°C in 6 months (direct freezing). The Uric Acid stability in urine samples at 20-25°C in 4 days. The urine samples should be diluted 1 to 10 by distilled water before assay the number should be multiply by 11. The pH of 24 hours' urine should adjust by add 15 ml of NaOH (5 molarity) to be 8 pH for avoiding any precipitation. Avoid any contamination, freezing and DE freezing the samples.

Required but not Supplied:
General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**
Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:
Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.
Maximum determination in this assay 30 mg/dl
LOD: 0.5 mg/dl
For samples with a higher concentration (30 mg/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

Precision:
Intra Assay-Within run Uric acid

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	4.46	0.02	0.46
2	20	10.37	0.05	0.44

Inter Assay-Between run Uric Acid

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	4.71	0.06	1.20
2	20	11.02	0.15	1.37

- **Accuracy:**
Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.9973
Regression equation: Y = 0.816 (X) + 0.319 mg/dl
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/l Bilirubin
Lipaemia	Less than 10% interference up to 1.25 g/l intralipid
Haemolysis	Less than 10% interference up to 1.25 g/l Hemoglobin.

Manufactured by: TOSE'E KIMIA SA'ADAT, No.5, 32nd Alley, Asadabadi St. Yousef abad, Tehran-IRAN
Factory Address: No.18, Niloufar 6, Toska Blvd., Nakhl Blvd., Paytakht Industrial Town, 54 km of Tehran-Semnan Road
Tel/Fax: +98 (0)21 88549754-9
www.tksmed.com - info@tksmed.com

Uric Acid (UA)
(Enzymatic/Uricase-POD Method)

- **Reference Values:**

Serum/Plasma	Girls	Boys
Infants – 5 days	1.9-7.9 mg/dl	1.9-7.9 mg/dl
Child 1-4 years	1.7-5.1 mg/dl	2.2-5.7 mg/dl
Child 5-11 years	3.0-6.4 mg/dl	3.0-6.4 mg/dl
Teenage 12-14 years	3.2-6.1 mg/dl	3.2-7.4 mg/dl
Teenage 15-17 years	3.2-6.4 mg/dl	4.5-8.1 mg/dl
Women	2.3-6.8 mg/dl	
Men	3.6-7.7 mg/dl	
24 hour Urine	250-750 mg/24h	

Each laboratory should establish its own expected values. The Uric Acid results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

520 (490-550) nm	**Wavelengths**
37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	Blank	
500 µl	500 µl	**R1**
25 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minutes at 37°C. Then added R2		

Control/Sample/Calibrator	Blank	
500 µl	500 µl	**R2**
Gently mix and incubate for 5 minutes at 37°C. The Absorbance A sample and A calibrator against Blank.		

Control/Sample/Calibrator	Blank	
1000 µl	1000 µl	**Single reference**
25 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minutes at 37°C. The Absorbance A sample and A calibrator against Blank.		

- **Calculations:**

Uric Acid serum/plasma(mg/dl) = Abs Sample X Conc. Cal. (mg/dl)
Abs Cal./STD.

In urine samples before assay the urine should be diluted 1 to 10 by distilled water.

Uric Acid urine(mg/dl) = Abs. Sample x Cal.Conc. (mg/dl) x 11
Abs. Cal./STD.

In urine 24 hours

Uric acid (g/24h) = Uric Acid Urine (mg/dl) x Urine Volume (ml)
100

Conversion Units:

Uric Acid(mg/dl) x 59.48 = Uric Acid (µmol/L)

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p.208-14.
2-Henry R.J.et., Clin.phatol.28 (1957)152.
3-Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999.p.1204-70.
4-Friedman R.B., et al. Clin Chem.,26(1988)211.
5-Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.
6-Schultz A. Uric acid. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1261-1266 and 418.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

ISO 13485:2016
ISO 9001:2015

IVD

Rev 01: Issued on 20 February 2023

Revised:20231129

Manufactured by: TOSE'E KIMIA SA'ADAT, No.5, 32nd Alley, Asadabadi St. Yousef abad, Tehran-IRAN
Factory Address: No.18, Niloufar 6, Toska Blvd., Nakhl Blvd., Paytakht Industrial Town, 54 km of Tehran-Semnan Road
Tel/Fax: +98 (0)21 88549754-9
www.tksmed.com - info@tksmed.com