TRUEchemie Uric Acid Test Kit (Uricase - POD)

for the quantitative determination of Uric acid in human serum or plasma or urine

INTENDED USE

The TRUEchemie Uric Acid Test Kit (Uricase - POD) is used for the quantitative determination of Uric acid in human serum or plasma or urine.

INTRODUCTION

Summary & Clinical Significance: Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukaemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs. The oxidation of uric acid provides for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid. A second approach, described by Praetorius and Poulson, utilizes the enzyme uricase to oxidise uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV masurement of the consumption of uric acid or in combination with other enzyme to provide a colorimetric method. The assay described here is a slight modification of the colorimetric method. The modifications were described by Siedel. In this reaction, the peroxide reacts in the presence of peroxidase, ADPS and aminoantipyrine to form a Blue purple quinoneimine dye. The intensity of the Blue purple color is proportional to the uric acid concentration and is determined photometrically.

PRINCIPLE

The enzymatic reaction sequence employed in the assay of uric acid is as follows:

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

$$H_2O_2 + \text{ADPS} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Blue color complex} + HCl + 4H_2O$$

PACK SIZE

Kit size	**2 x 50 ml**
Cat. no.	**ADX252**
Kit contents	
1) Uric Acid Reagent	2 x 50 ml
2) Uric Acid Standard (10 mg/dL)	1 x 5 ml

REAGENT COMPOSITION

1) Uric Acid Reagent

4-Aminoantipyrine	:	4 mmol/L
3,5 Dichloro-2- hydroxybenzene sulfonate:		2 mmol/L
Stabilizer and surfactant		
Buffer pH	:	7.5

2) Uric Acid Standard : 10 mg/dL

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

1. Serum (free from hemolysis) (or) plasma (or) urine.
2. Bacterial contamination should be avoided to preserve the loss of uric acid.
3. Uric acid in serum is stable for three (3) days at 2 - 8 °C and up to six (6) months when frozen.
4. Urine should be diluted 1:10 with distilled water before use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 546 nm

TEST PROCEDURE

Wavelength	:	546 nm
Temperature	:	37°C

Prewarm the reagent to reaction temperature.

	Blank (µl)	Standard (µl)	Sample (µl)
Uric acid Reagent	1000	1000	1000
Uric acid Standard	--	25	--
Sample	--	--	25

Incubate all tubes at 37°C for 5 minutes or 10 minutes at RT. After incubation, zero the photometer with the reagent blank at 546 nm. Read and record the incubated standards and samples.

$$\text{Calculation} = \frac{\text{Sample OD}}{\text{Standard OD}} \times 10 \text{ mg Uric acid/dL}$$

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Men	:	3.4 - 7.0 mg/dL
Women	:	2.4 - 5.7 mg/dL
Urine	:	250 -750 mg/24 hrs.

It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: upto 0.03 mg/dL.
Linearity: upto 30 mg/dL under the described assay conditions. If the concentration is greater than linearity (30 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision Within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	4.81	0.02	0.51
Control Level - 2	9.74	0.06	0.58

Inter-assay precision Run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	4.82	0.04	0.81
Control Level - 2	9.68	0.03	0.34

The reagent was tested for 12 days, using two different Uric acid concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Uric acid reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.999 and the regression equation is y=0.987x+0.160. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No significant interference was observed from Bilirubin up to 25 mg/dL (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dL, Lipemia as Triglycerides up to 2000 mg/dL, Ascorbic acid up to 100 mg/dL.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. conc.	:	10
Wave length	:	546 nm
Units	:	mg/dL
Flow cell temp.	:	37°C
Blank	:	Reagent
Reagent volume	:	1000 µl
Sample volume	:	25 µl
Incubation	:	5 min at 37°C
Low normal	:	2.4
High normal	:	7.0
Sensitivity	:	0.03
Linearity	:	30
Reaction Slope	:	Increasing

REFERENCES

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2. Colombo J-P (ed) Klinisch -chemische Urindiagnostik. Rotkreuz: Labolive-. -,Verlagsgesellschaft 1994:18.0
3. DiGiorgio J; Henry RJ, et al eds. Clinical Chemistry: Principles and Technics. 2nd ed. New York NY; Harper and Row; 1974:532.
4. El king SM, Kabat HF. Am Soc Hosp Pharm. 1969;25:485.
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7. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C 8°C Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry

Do not use if package is damaged — Keep away from sunlight

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