Uric Acid FS
Uric Acid Reagent Test Kit

Intended Use:
Diagnostic reagent for in vitro quantitative determination of Uric acid in human serum or plasma on photometric analyzers.

Order Information

Item Code	Pack Size
130219934840	R1 : 4 x 60 mL, R2 : 4 x 15 mL

Summary [1, 2]
Uric acid and its salts are end products of the purine metabolism. In goutaell 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.

Method
Enzymatic photometric test

Principle
Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with 4-aminoantipyrine and 2, 4, 6-tribromo-3-hydroxybenzoic acid (TBHBA) to quinoneimine.

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

$$\text{TBHBA} + \text{4-Aminoantipyrine} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Quinoneimine} + 3\,H_2O$$

Reagents

Components and Concentrations

R1:	Disodium Hydrogen Phosphate	2.5g/L
	Uricase	>50 U/L
	POD	>1kU/L
R2:	Potassium Dihrogen Phosphate	8g/L
	Disodium Hydrogen Phosphatel	20g/L
	Preservatives & Stabilizers	q.s.

Trceability of values

The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). DiaSys TruLab N and P controls should be assayed for internal quality control.

Storage Instructions and Reagent Stability

The reagents and the standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8℃, protected from light and contamination is avoided. Do not freeze the reagents!

Note: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the monoreagent is < 0.5 at 546 nm.

Warnings and Precautions

1. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment
TruCal U (591009910064)
TruLab N (590009910061)
TruLab P (590509910061)

Specimen collection, handling & Storage
Serum, heparin plasma or EDTA plasma, urine

Stability in serum/plasma [3]:
6 months at –20℃
7 days at 4 – 8℃
3 days at 20 – 25℃ Freeze only once.
Discard contaminated specimens.

Stability in urine [4]:
4 days at 20 – 25℃
Dilute urine 1 +10 with dist. water and multiply the results by 11.
Discard contaminated specimens.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	520 nm, 546 nm, 500 - 550 nm
Optical path	1 cm
Temperature	20 – 25℃/ 37℃
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or	-	20 µL
Dist. water	20	-
Reagent 1	1000	1000 µL
Mix, incubate 5 min., then add:		
Reagent 2	250 µL	250 µL Mix,
incubate 30 min. at 20 – 25℃ or 10 min. at 37 ℃.		
Read the absorbance against the reagent blank within 60 min.		

Calculation
With standard or calibrator

$$\text{Uric acid [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}$$

Conversion factor
Uric acid [mg/dL] x 59.48= Uric acid [µmol/L]

Calibrators and Controls
For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring range

The test has been developed to determine uric acid concentrations within a measuring range from 0.07 – 20 mg/dL (4.2 – 1190 µmol/L). When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences

No interference was observed by bilirubin up to 10 mg/dL and lipemia up to 2000 mg/dL triglycerides. Hemoglobin interferes starting with a concentration of 100 mg/dL. Ascorbic acid interferes even in minimal concentrations.

Sensitivity/Limit of Detection

The lower limit of detection is 0.07 mg/dL.

Precision (at 37°C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	5.54	0.08	1.49
Sample 2	5.13	0.02	3.97

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	7.48	0.12	1.58
Sample 2	8.28	0.08	0.96

Method Comparison

A comparison of DiaSys Uric acid FS TBHBA (y) with a commercially available test (x) using 70 samples gave the following results: y = 1.02 x – 0.44 mg/dL; r= 0.997

Interpretation of the results
Serum/Plasma

	Female mg/dL (µmol/L)	Male mg/dL (µmol/L)
Adults [5]	2.6 – 6.0 (155 – 357)	3.5 – 7.2 (208 – 428)
Children [6]		
1 – 30 days	1.0 – 4.6 (59 – 271)	1.2 – 3.9 (71 – 230)
31 – 365 days	1.1 – 5.4 (65 – 319)	1.2 – 5.6 (71 – 330)
1 – 3 year(s)	1.8 – 5.0 (106 – 295)	2.1 – 5.6 (124 – 330)
4 – 6 years	2.0 – 5.1 (118 – 301)	1.8 – 5.5 (106 – 325)
7 – 9 years	1.8 – 5.5 (106 – 325)	1.8 – 5.4 (106 – 319)
10 – 12 years	2.5 – 5.9 (148 – 348)	2.2 – 5.8 (130 – 342)
13 – 15 years	2.2 – 6.4 (130 – 378)	3.1 – 7.0 (183 – 413)
16 – 18 years	2.4 – 6.6 (142 – 389)	2.1 – 7.6 (124 – 448)

Urine [1]
≤800 mg/24h (4.76 mmol/24h) assuming normal diet
≤600 mg/24h (3.57 mmol/24h) assuming low purine diet
Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Limitations:

Result interference can be seen for patient sample results above 2000 mg/dL.

Literature

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8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240–1243.

Notes on Symbols and Marks

	Consult instruction for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CONT.	The pack contains
	Recycle
	Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

DiaSys Diagnostics India Private Limited
Plot No. A – 821, T.T.C. Industrial Area, MIDC,
Mahape, Navi Mumbai – 400710.
Maharashtra, India.

Customer Care
For feedback/queries contact customer care at :
Toll Free number : 1800 120 1447
Email ID : helpdesk.service@diasys.in
Website : www.diasys.in

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