URIC ACID (UA)

546 nm
Enzymatic Colorimetric Method
RX SERIES

INTENDED USE

For the quantitative *in vitro* determination of Uric Acid in serum, plasma and urine. This product is suitable for use on the RX **series** instruments which includes the RX **daytona** and RX **imola**.

Cat. No.		
UA 3824	R1. Reagent	6 x 51 ml
	R2. Starter	4 x 20 ml

GTIN: 05055273206739

CLINICAL SIGNIFICANCE

Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients receiving cytoxic drugs.

COLORIMETRIC METHOD[1,2]

Uric Acid is converted by uricase to allantoin and hydrogen peroxide, which under the catalytic influence of peroxidase, oxidizes TOOS* and 4-aminophenazone to form a red-violet quinoneimine compound.

PRINCIPLE

$$\text{Uric Acid} + 0_2 + 2H_20 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_20_2$$

$$2H_20_2 + H^+ + \text{TOOS*} + \text{4-aminophenazone} \xrightarrow{\text{peroxidase}} \text{quinone di-imine dye} + 4H_2O$$

*TOOS =
N-ethyl-N-(2-Hydroxy-3-sulfopropyl)-3-methylaniline

SAMPLE COLLECTION AND PREPARATION[3]

Serum, heparinized plasma or EDTA-plasma. Normal procedures for collecting and storing serum and plasma may be used for samples to be analysed by this method. Uric acid is stable in serum for up to 5 days when stored between +2 to +8°C and for 6 months when stored at -20°C. Urine samples are diluted automatically on board the analyser. Results are automatically recalculated.

REAGENT COMPOSITION

Contents		Concentrations in the Test
R1.	**Reagent**	
	Phosphate Buffer	50 mmol/l, pH 7.0
	Toos*	7.0 mmol/l
	Ascorbate Oxidase	≥ 5 U/ml
R2.	**Starter**	
	Phosphate Buffer	50 mmol/l, pH 7.0
	4-Aminophenazone	0.3 mmol/l
	Peroxidase	≥1000 U/l
	Uricase	≥ 200 U/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solutions R1 and R2 contain 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.

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.

Health and Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1. Reagent
Contents ready for use. The reagent is stable, if unopened, up to the expiry date specified. Store protected from light.

R2. Starter
Contents ready for use. The contents are stable, if unopened, up to expiry date specified. Store protected from light.

MATERIALS PROVIDED

Reagent
Starter

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)

PROCEDURE NOTES

If measurement of urine samples is required, please ensure that the separate urine program on the parameters disc is used.

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

CALIBRATION
The use of Randox Calibration Serum Level 3 is recommended for calibration.

STANDARDISATION
Randox Calibration Serum Level 3 is traceable to Uric Acid reference method ID-GC/MS.

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 cleanliness of all equipment in use.
3. Check water. Contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERENCE
The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	1000 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid®	600 mg/dl
Ascorbic Acid	6 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [6]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES[3,4]

Serum:	Men	202 - 416 µmol/l
		3.4 - 7.0 mg/dl
	Women	142 - 339 µmol/l
		2.4 - 5.7 mg /dl
Urine:		1.5 - 4.5 mmol/24 hours
		250 - 750 mg /24 hours

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following performance characteristics were obtained using the RX **daytona**.

SERUM

LINEARITY
The method is linear to a concentration of 1375 µmol/l (23.1 mg/dl), or 2292 µmol/l (38.5 mg/dl) in the event of a rerun.

SENSITIVITY
The minimum detectable concentration of Uric acid with an acceptable level of precision was determined as 20.8 µmol/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (µmol/l)	92.7	293	574
SD	3.13	8.57	11.1
CV (%)	3.38	2.92	1.94
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (µmol/l)	90.6	288	579
SD	1.44	3.08	6.00
CV (%)	1.59	1.07	1.03
n	20	20	20

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y =1.03 X - 5
and a correlation coefficient of r = 0.99

40 patient samples were analysed spanning the range 191 to 539 µmol/l.

URINE

LINEARITY
The method is linear to a concentration of 14304 µmol/l (240 mg/dl), or 30038 µmol/l (504 mg/dl) in the event of a rerun.

SENSITIVITY
The minimum detectable concentration of Uric acid with an acceptable level of precision was determined as < 129.5 µmol/l.

PRECISION

Intra Assay

	Level 1	Level 2	Level 3
Mean (µmol/l)	629	2668	7114
SD	21.07	52.0	103.15
CV (%)	3.35	1.95	1.45
n	20	20	20

Inter Assay

	Level 1	Level 2
Mean (µmol/l)	655	2679
SD	29.5	58.7
CV (%)	4.43	2.19
n	20	20

REFERENCES
1. Barham, D., and Trinder, P., Analyst (1972) **97**, 142-145.
2. Fossati, P., Prencipe, L., and Berti, G., Clin. Chem. (1980) **26/2**, 227-231.
3. Tietz, NW, Textbook of clinical chemistry, W.B. Saunders, Co., Philadelphia, P.A. (1994) pp 58-69 (specimen collection and storage recommendations). P2210 (reference values).
4. Thefeld, W. *et al.* Dtsch. Med. Wschr. (1973) **98**, 380.
5. Krieg, M. *et al.* J. Clin. Chem. Clin. Biochem.(1986) **24**, 863.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a Technical update from the previous revision.

EC REP

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