UREA

Enzymatic Kinetic Method
RX SERIES

INTENDED USE

A urea test system is a device intended for the quantitative *in vitro* determination of urea concentration 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.

UR 3825	R1. Coenzyme	6 x 51 ml
	R2. Enzymes/Substrate	4 x 20 ml

GTIN: 05055273206906

CLINICAL SIGNIFICANCE

Urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

UV METHOD [1, 2]

Urea is hydrolysed in the presence of water and urease to produce ammonia and carbon dioxide. The ammonia produced in the first reaction combines with α-oxoglutarate and NADH in the presence of glutamate-dehydrogenase to yield glutamate and NAD^+.

PRINCIPLE

$$\text{Urea} + H_20 \xrightarrow{\text{Urease}} 2NH_4^+ + CO_2$$

$$2\alpha\text{-oxoglutarate} + 2NH_4^+ + 2NADH \xrightarrow{\text{GLDH}} \text{2L-glutamate} + 2NAD^+ + 2H_2O$$

SPECIMEN COLLECTION AND PREPARATION [3,4]

Serum/Plasma: Heparin may be used as an anticoagulant. Do not use ammonium heparinate.

Urine (24h): Collect urine without additives: refrigerate after collection
A 1 + 20 dilution with 0.9% NaCl solution is automatically carried out by the analyzer if the urea urine program is used. Results are adjusted for the dilution automatically.

Urea is stable in serum/plasma for 1 day at +25°C, 3 days at +2°C to +8°C or 3 months at -20°C.
Urea is stable in urine for 4 days when stored at +2°C to +8°C.

REAGENT COMPOSITION

Contents		Initial Concentration of the Solution
R1	**Coenzyme**	
	Capso Buffer	5 mmol/l, pH 9.65
	NADH	≥ 0.23 µmol/l
R2.	**Enzymes/Substrate**	
	Bicine Buffer	1 mol/l
	Urease	≥ 16.2 U/ml
	GLDH	≥ 0.9 U/ml
	α-oxoglutarate	≥ 8.6 mmol/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.

Solution R1 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.

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.

Safety Data Sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines

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 Coenzyme
Contents ready for use. Stable up to the expiry date when stored at +2°C to +8°C.

R2 Enzymes/Substrate
Contents ready for use. Stable up to the expiry date when stored at +2°C to +8°C.

MATERIALS PROVIDED

Urea Reagent

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).

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

PROCEDURE NOTES

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
0.9% NaCl solution and Randox Calibration Serum Level 3 are recommended for calibration.

STANDARDISATION
Randox Calibration Serum Level 3 is traceable to Urea reference material NIST 909b.

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.

LIMITATIONS [5,6]
Great care must be taken to prevent ammonia contamination of the specimens to be analysed for urea. Ammonia in the atmosphere, in the room, in the water or in the reagent will elevate test results.
A list of substances and conditions known to affect urea levels *in vivo* is given by both Young *et al*[5] and Friedman *et al*[6]. No representation is made by Randox Laboratories Ltd regarding the completeness of these lists or the accuracy of the information contained therein.

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	750 mg/dl
Intralipid®	200 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 [8]. 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[7]
Serum	1.7 - 8.3 mmol/l (10 - 50 mg/dl)
Urine (24 Hour)	333-583 mmol/l (20-35 g/24 h)

Since normal ranges are affected by age, sex, diet, geographical location and other factors, each laboratory should establish its own expected values for this procedure.

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

SERUM

LINEARITY
The method is linear to 50.5 mmol/l (303 mg/dl) in serum or plasma. In the event of a rerun the method is linear up to 126.5 mmol/l (760 mg/dl) in serum or plasma.

SENSITIVITY
The minimum detectable concentration of Urea with an acceptable level of precision was determined as 0.510 mmol/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	3.15	7.08	19.4
SD	0.120	0.211	0.302
CV(%)	3.82	2.98	1.56
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	3.30	6.69	19.1
SD	0.147	0.292	0.302
CV(%)	4.46	4.37	1.58
n	20	20	20

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

Y = 1.01 X + 0.08
and a correlation coefficient of R = 0.99.

40 patient samples were analyzed spanning the range 2.55 to 21.6 mmol/l.

URINE

LINEARITY
The method is linear to 932 mmol/l (5599 mg/dl). In the event of a rerun the method is linear up to 2330 mmol/l (13997 mg/dl).

SENSITIVITY
The minimum detectable concentration of Urea with an acceptable level of precision was determined as 109 mmol/l

PRECISION

Intra Assay

	Level 1	Level 2	Level 3
Mean (mmol/l)	292	549	830
SD	13.78	19.48	28.8
CV(%)	4.72	3.55	3.48
n	20	20	20

Inter Assay

	Level 1	Level 2	Level 3
Mean (mmol/l)	284	478	863
SD	7.1	8.56	19.93
CV(%)	2.5	1.79	2.31
n	20	20	20

REFERENCES:

1. Marshall EK Jr: J Biol Chem 1913; **15**:487.
2. Talke H; Schubert GE: Klin Wschr 1965; **43**:174.
3. Tietz N. W., Textbook of Clinical Chemistry. W.B. Saunders Co, 1987, 1254-1316.
4. Tietz N.N: Clinical Guide to Laboratory Tests Philadelphia. W.B. Saunders Co, 1983 pg 494.
5. Young D.S., Pestaner, L.C., Gibbermann, V. Clin. Chem, 1975; **21**: No5.
6. Friedmann R.B, *et al*: Clin Chem 1980; **26** No4.
7. Kerscher,L; Tieqenhorn,J; "Methods of enzymatic Analysis", H.U. Bergmeyer Ed., VCH Verlagsgesellschaft, Weinheim, 1985 3rd Ed; Vd VII, p453.
8. 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 Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland

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