ROBONIK®

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prietest™ ...Clinical Chemistry Reagents

UREA (GLDH-UV KINETIC)

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of concentration of Urea in serum or plasma on photometric systems.

ORDERING INFORMATION

Pack Size	Cat No.
2 X 25 ml	URUV 02 25
4 X 50 ml	URUV 04 50
2 X 500 ml	URUV 02 500

CLINICAL SIGNIFICANCE : Urea is the major metabolite product of protein catabolism. The biosynthesis of urea from ammonia is exclusively carried out by hepatic enzymes. More than 90% of urea is excreted through the kidneys, with the remainder excreted through the gastrointestinal tract or skin. Blood urea concentrations can be increased by numerous factors linked to prerenal causes (increased protein catabolism, as in haemorrhage into gastrointestinal tract, shock, some chronic liver diseases) or renal/postrenal causes (acute or chronic renal diseases, postrenal obstruction to urine flow).

Uremia is also increased by high-protein diet, state of dehydratation, muscle wasting (as in starvation). The determination of urea rate is used together with the determination of creatinine rate to discriminate between prerenal (normal creatinine) and renal/postrenal (increased creatinine) disorders.

METHOD :

Enzymatic - UV, Kinetic

PRINCIPLE :

Enzymatic determination according to the following reactions :

$$Urea + 2H_2O \xrightarrow{Urease} 2NH_4^+ + Co_3^{2-}.$$

$$NH_4^+ + Tris\ Base + NADH \xrightarrow{GLDH} L\text{-}Glu + NAD^+ + H_2O$$

REAGENTS :

R1:

Tris Base	:	120mmol/l
2 - Oxo Glutarate	:	7 mmol/l
Urease	:	>6KU/l
Glutamate Dehydrogenase	:	> 1 KU/l

R2:

NADH	:	0.25 mmol/l
Preservative and Stabilizer		
Standard	:	40 mg/dl (6.66 mmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagent!

WARNINGS AND PRECAUTIONS :

Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :

Please refer to local regulation requirements.

REAGENT PREPARATION :

The standard is ready-to-use.

Mono-reagent procedure

Mix 4 volumes of reagent 1 (R1) with 1 volume of reagent 2 (R2).

Stability : 4 weeks at 2 to 8°C.

Two-Reagent procedure

The reagents are ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :

NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :

Serum or heparinized plasma. Urines should be diluted at 1: 20 to 1: 50 with distilled water before analysis.

Storage : Serum and plasma are stable up to 24 hours at room temperature, for one week at 4°C. Frozen between –15 to –20°C, these samples are stable for at least 2 to 3 months.

Urine samples are stable up to 4 days if stored at 4 to 8°C. Urine can be preserved with thymol to avoid bacterial action or by maintaining the pH below 4.

ASSAY PROCEDURE: Two Reagent Procedure

Application sheets for automated systems are available on request.

Wavelength	:	Hg 340 nm
Temperature	:	37°C
Cuvette	:	1 cm light path
Read Against	:	Distilled Water
Mode	:	Fixed Time / Initial Rate

Bring all the contents of the kit to Room Temperature prior to use.

Read rate of change of absorbance of sample against distilled water.

Label the test tube as standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

Prewarm reagent at 37°C for 2 minutes.

	Standard	Sample / Control
R1	800 µl	800 µl
R2	200 µl	200 µl

Mix and Incubate at 37°C for 2 minutes then add

Standard	10 µl	—
Sample / Control	—	10 µl

Mix and read the variation of absorbance (ΔA) between 30 seconds and 60 seconds.

Mono Reagent Procedure

Prewarm working reagent at 37°C for 2 minutes.

	Standard	Sample / Control
Working Reagent	1000 µl	1000 µl
Standard	10 µl	—
Sample / Control	—	10 µl

Mix and read the variation of absorbance (ΔA) between 30 seconds and 60 seconds.

CALCULATION :

With standard or calibrator.

$$\text{Concentration in Sample (mg/dl)} = \frac{\text{Concentration of Standard}}{\Delta A \text{ Standard}} \times \Delta A \text{ Sample}$$

CONVERSION FACTOR :

Urea [mg/dl] X 0.1665 = Urea [mmol/l]

Urea [mg/dl] / 2.14 = BUN [mg/dl] *(Blood Urea Nitrogen)*

CALIBRATION :

For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :

To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE : The test has been developed to determine Urea concentrations within a measuring range from 2 to 300 mg/dl (0.333 to 50 mmol/L). When values exceed higher limit of the 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 20 mg/dl (427 µmol/L) and lipemia up to 600 mg/dl (6.84 mmol/L) triglycerides, Hemoglobin 0.5 g/dl (5 g/L), Ascorbic Acid 20 mg/dl (1136 µmol/L). A list of drugs and other interfering substances with Urea determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :

The lower limit of detection is 2 mg/dl (0.333 mmol/L).

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	73.6	0.72	0.98
Sample 2	185.35	1.66	0.90
Sample 3	51.0	0.40	0.78

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	158	1.0	0.63
Sample 2	61.0	0.5	0.82
Sample 3	148	1.0	0.68

METHOD COMPARISON :

A comparison between Robonik prietest Urea (GLDH-UV KINETIC) (y) and a commercially available test (x) using 20 samples gave following results :

Linear Regression	:	y = 0.9288x + 2.7096 mg/dl
Correlation Coefficient	:	r = 0.8993

REFERENCE RANGE :

Serum / Plasma	:	13 to 43 mg/dl	(2.16 to 7.16 mmol/L)
Urine	:	26 to 43 g/24hrs.	(430 to 710 mmol/24h)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Newman, D.J., Price C.P., *Non protein Nitrogen Metabolite*. Tietz Fundamentals of Clinical Chemistry, 5 th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 414.
2. Tietz, N.W., Clinical guide to laboratory tests, 3rd Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 622.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION
prietest TOUCH

Name : UREA , Mod : FIX_T
Pri.: 340 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : mg/dl
Lag : 30 , Read : 60
Blk : N, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 40
Normal HI = 43
Normal LO = 13
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Init. OD : = 1.0 L
Max Delta : = 0.5
Rgnt. Linearity : 300
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING

TEST NAME	UREA
Reaction	Fixed Time
Reaction Slope	Decreasing
Wavelength 1	340 nm
Temperature	37°C
Zero Setting	Distilled Water
Lag Time	30 seconds
Read Time	60 seconds
Standard Conc.	40
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Reference Range	13 to 43
Reagent Linearity	300
Initial OD	> 1.0
Max Delta	0.5

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