ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

UREA (Mod. Berthelot)

In vitro diagnostic test kit, for professional use only

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

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	2 X 50 ml	URMB 02 50
	4 X 50 ml	URMB 04 50
	2 X 500 ml	URMB 02 500

CLINICAL SIGNIFICANCE : Urea is produced in the liver as a waste product in the urea cycle from catabolism of proteins in humans. Consequently the circulation levels of urea depend upon protein intake, protein metabolism and kidney function. Low levels of urea are not common. It can be seen in severe liver disease or malnutrition but are not used to diagnose or monitor these conditions. Low urea level is also occurred in normal pregnancy. Elevated level of urea suggest impaired kidney function but it may also due to congestive heart failure, shock, recent heart attack or severe burns, bleeding from gastrointestinal tract and conditions that cause obstruction of urine flow or dehydration.

METHOD :
Photometric test Enzymatic according to modified Berthelot, End Point.

PRINCIPLE :

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_3 + Co_2$$

$$NH_3 + \text{Salycilate} + \text{Hypochlorite} \xrightarrow{\text{Nitroprusside}} \text{2-2-Dicarboxy Indophenol}$$

In an alkaline medium, in the presence of salicylate and sodium hypochlorite, ammonium ions react to produce a blue green color compound.

REAGENTS :

COMPONENTS AND CONCENTRATIONS:
N.B: Concentrations are those in the final test mixture.

R1	Sodium Salicylate	:	62.5 mmol/l
	Sodium Nitro Prusside	:	5 mmol/l
R2	Urease	:	> 4 U/ml
	Preservative & Stabilizer		
R3	Sodium Hypo Chlorite	:	> 6 mmol/l
	Preservative & Stabilizer		
Standard		:	40 mg/dl (6.66 mmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents and the standard 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 reagents!

WARNINGS AND PRECAUTIONS :
Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The Reagent and standard is ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Serum/Plasma: Use non-haemolyzed serum, heparinized or EDTA plasma
(Do not use ammonium salt and sodium fluoride as anticoagulants).
Urine: A 1: 20 dilution of urine with ammonia free water is typically required prior to analysis.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.

Wavelength	:	Hg 578 nm, 600 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Chromogen Soln R1	500 µl	500 µl	500 µl
Enzyme Soln. R2	50 µl	50 µl	50 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and incubate for 3 minutes at 37°C. Then add Hypochlorite Soln. in to respective label tubes as given below

	Blank	Standard	Sample / Control
Hypochlorite Soln. R3	500 µl	500 µl	500 µl

Mix and read the absorbance (A) after a 5 minutes incubation but within 30 minutes.

CALCULATION :
With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard} - \text{Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

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, such 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 25 mg/dl (427.6 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 (1135.6 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	117.20	0.88	0.75
Sample 2	73.66	0.72	0.98
Sample 3	185.34	1.66	0.90

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	158	1.0	0.63
Sample 2	61	0.5	0.82
Sample 3	148	1.0	0.68

METHOD COMPARISON :
A comparison between Robonik Prietest Urea (Modified Berthelot) (y) and a commercially available test (x) using 20 samples gave following results:

Linear Regression	:	y = 0.9704x + 0.6545 mg/dl
Correlation Coefficient	:	r = 0.9930

REFERENCE RANGE :

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

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

LITERATURE :

1. Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz fundamentals of Clinical Chemistry. 5th ed.
2. First, M.R. Renal Function. Clinical Chemistry : Theory. Analysis. Correlation. 4th Ed.
3. Vassault, A., et. al, Ann. Biol. Clin. (1986) 44, 686

INSTRUMENT APPLICATION
prietest TOUCH

Name : UREA, Mod : END-P
Pri.: 578 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : mg/dl
Lag : 5 , Read : NA
Blk : Y, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 40
Normal HI = 43
Normal LO = 13
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Rgnt. Linearity : 300
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	UREA
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	578 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	40
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1050 µl
Incubation Time	3+5 minutes
Reference Range	13 to 43
Reagent Linearity	300

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