UREA TEST KIT (Mod.Berthelot)

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

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 diseases 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 suggested impaired kidney function but it may also due to congestive heart failure, shock, recent heart attack or severe burns, bleeding from gastrointestinal track and conditions that cause obstruction of urine flow or dehydration.

PRINCIPLE : Photometric, enzymatic test according to modified Berthelot, End Point.

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

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

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

REAGENT COMPOSITION :
R 1 : Chromogen Solution
R 2 : Enzyme Solution
R 3 : Hypochlorite Solution
Urea Standard : 40 mg/dl

MATERIAL REQUIRED BUT NOT PROVIDED :
- Clean & dry Glassware
- Micropippete & tips.
- Colorimeter or Bio Chemistry Analyser.

SAMPLES : Serum, heparinised plasma or EDTA plasma.

STABILITY OF REAGENT: The reagents and the standard are stable up to indicated date of expiry on the label, if stored at 2 to 8°C, protected from light and contamination if avoided. Do not freeze the reagents.

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

ASSAY PROCEDURE :

	Blank	Standard	Sample/Control
Chromogen Soln R1	500 µl	500 µl	500 µl
Enzyme soln R2	50 µl	50 µl	50 µl
Standard	------	10 µl	------
Sample/ Control	------	------	10 µl

Mix and incubate for 3 minutes at 37°C. Then add Hypochlorite Soln. in to respective 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 at 37°C against Reagent Blank.

GENERAL SYSTEM PARAMETERS :

Test Name	Urea
Reaction	End Point
Reaction Slope	Increasing
Wavelength	578 nm
Temperature	37°c
Zero Setting	Reagent Blank
Standard Conc.	40 mg/dl
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1050 µl
Incubation Time	3+5 Minutes
Reference Range	13 To 43 mg/dl
Reagent Linearity	300 mg/dl

CALCULATION :

$$C = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 40 \text{ mg/dl}$$

LINEARITY : Reagent is Linear upto 300 mg/dl .Dilute the Sampl appropriately and re-assay if urea conc. exceeds 300 mg/dl. Multiply result with dilution factor.

REFRENCE NORMAL VALUE :
Serum/Plasma : 13 to 43 mg/dl
Urine : 26 to 43 g/24 Hrs.

QUALITY CONTROL : For Accuracy it is necessary to run known controls with every essay.

SENSITIVITY / LIMIT DETECTION : The Lower Limit of detection is 2 mg/dl.

LIMITATION & PRECAUTIONS :
- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Before the assay bring all the reagents to room temperature.
- Avoid contamination of the reagent during assay process.
- Every time use new pipette-tips for pipetting out the reagents.
- These Reagent kits meant for laboratory/professional use only, not for Drug use.

BIBLIOGRAPHY :
Expert Panel on enzyme of the ifcc, Clin Chem. Acta, 70, PM (1976), Teitz.,N.W.

Mfd. In India By:
PRECILAB REAGENTS & CHEMICALS PVT. LTD.
A / F-6 & F-8, Udyog Bhawan - 2, Plot K - 3, MIDC,
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