



**Asritha**

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## UREA KIT

(Mod. Berthelot Method)

For the determination of Urea in serum plasma and urine.

(For In vitro Diagnostic Use Only)

### CLINICAL SIGNIFICANCE

Urea is the end product of the protein metabolism. It is synthesized in the liver from ammonia produced by the catabolism of amino acids. It is transported by the blood to the kidneys from where it is excreted.

### INCREASES

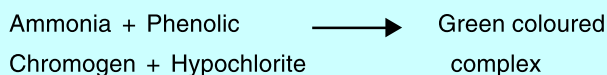
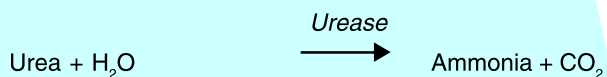
Increased levels are found in renal diseases, urinary obstructions, shock, congestive heart failure and burns.

### DECREASES

Decreased levels are found in liver failure and pregnancy.

**METHODOLOGY** – Modified Berthelot method.

### PRINCIPLE



Intensity of the colour formed is directly proportional to the amount of urea present in the sample.

### REAGENT COMPOSITION

Urease	30,000 U/L
Sodium Hypochlorite	10 mmol/L
NaOH	400 mmol/L
Sodium Salicylate	40 mmol/L
Activator & Stabilizers	

**STANDARD CONCENTRATION** - 40 mg/dl

### STORAGE/STABILITY

Contents are stable at 2 - 8° C till the expiry mentioned on the labels.

### REAGENT PREPARATION

Reagents are ready to use for the given procedure.

### WORKING ENZYME REAGENT (WR)

For the flexibility and convenience in performing large assay series, a working enzyme reagent may be made by pouring 1 bottle of A2 (Enzyme Reagent) into 1 bottle of A1 (Buffer Reagent).

Working reagent is stable for 16 weeks when proper storage conditions are strictly maintained.

### SAMPLE MATERIAL

Serum, plasma or urine. Dilute urine 1 + 49 distilled/deionised water before the assay (Results x 50). Urea is reported to be stable in the serum for 5 days when stored at 2 - 8° C.

### ASSAY PARAMETERS

<b>Reaction</b>	End point	<b>Interval</b>	-
<b>Wavelength</b>	570 nm	<b>Sample Vol.</b>	0.01ml
<b>Zero Settings</b>	Reagent Blank	<b>Reagent Vol.</b>	2.00ml
<b>Incub. Temp</b>	37°C/R.T.	<b>Standard</b>	40 mg/dl
<b>Incub Time</b>	8 min / 15 min	<b>Factor</b>	-
<b>Delay Time</b>	-	<b>React. Slope</b>	Increasing
<b>Read Time</b>	-	<b>Linearity</b>	300 mg/dl
<b>No. of read.</b>	-	<b>Units</b>	mg/dl

### ASSAY PROCEDURE

Wavelength / filter	:	570 nm (Hg 578 nm) Yellow
Temperature	:	37°C / R.T.
Light Path	:	1 cm

Pipette into clean dry test tubes labelled as Blank (B), Standard (S), and Test (T):

Addition Sequence	B	S	T
Working Enzyme Reagent (WR)	1.0 ml	1.0 ml	1.0 ml
Urea Standard	-	0.01 ml	-
Specimen	-	-	0.01 ml
Mix and incubate for 3 minutes at 37°C (5 mins. At R.T)			
Chromogen Reagent	1.0 ml	1.0 ml	1.0 ml

Mix and incubate for 5 minutes at 37° C (10 min at RT) Measure the absorbance of the Standard (Abs.S), and Test Sample (Abs.T) against Blank (B), at 578 nm (570-620nm)

The final colour is stable 10 hrs at R.T.

#### CALCULATIONS

$$\text{Urea in mg/dl} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 40$$

#### LINEARITY

The procedure is linear upto 300 mg/dl. If values exceed this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay. Calculate the value using the proper dilution factor.

#### NOTE:

- Enzyme Reagent(A2) may appear slightly hazy, but after mixing it with Buffer Reagent (A1) its haziness disappears and this does not affect the performance of kit..
- Any contamination by ammonia or ammonium salts lead to erroneous results, hence plasma should not be collected within Fluoride or Heparin ammonium salts.
- The working enzyme reagent is not stable at elevated temperatures and should be stored back at 2 - 8° C immediately after use.
- The chromogen reagent contains chlorine. The bottles should be opened only when required and closed tightly after use to prevent the loss of active chlorine.

#### QUALITY CONTROL

To ensure adequate quality control each run should include assayed normal & abnormal controls.

#### NORMAL VALUES

Serum, Plasma	:	14 – 40 mg/dl
Urine	:	Upto 20g/L

It is recommended that each laboratory establish its own normal range representing its patient population

#### REFERENCES

- Berthelot, M.P.E, (1859) Report chim. Appl. 2884
- Fawcett, J.K. Scott, J.E., (1960) J.Chim. Pathol. 13:156

#### PRESENTATION

PRODUCT CODE	PACK SIZE	ENZYME REAGENT (A <sub>2</sub> )	BUFFER REAGENT (A <sub>1</sub> )	CHROMOGEN REAGENT (A <sub>3</sub> )	STANDARD (S)
AUB 0630	2 x 60ml	3ml	60ml	60ml	5.0ml
AUB 0631	2 x 110ml	6 ml	110ml	110ml	5.0ml

#### PRODUCT FEATURES AT A GLANCE :

- Liquid stable two Reagent system.**
- Highest Linearity 300 mg/dL.**
- Urea & BUN value can be calculated.**
- No interference from Hemoglobin and Bilirubin.**
- Suitable for colorimeter and Analyzers.**
- Results comparable with other Enzymatic methods like Urea (GLDH).**
- Shelf life – 24 months.**
- Convenient pack size – 2 x 60 ml, 2 x 110 ml.**



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## ASRITHA DIATECH INDIA PVT. LTD.

IN VITRO DIAGNOSTIC REAGENTS

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