

Reagent kit for quantitative estimation of Urea in Serum or Plasma.

DIAGNOSTIC SIGNIFICANCE:

Urea is the end product of Protein degradation. High level of Urea is responsible for Kidney Failure, Shock, Urine Retention, Liver disease. It is also increased in adrenocortical insufficiency. Decreased level found in malnutrition, hepatic failure, pregnancy.

PRINCIPLE:

Urea is acted upon by urease releasing ammonia and Carbon dioxide. The Ammonia generated is utilised by Glutamate Dehydrogenase (GLDH) in the presence of 2-Oxoglutarate (α -KG) to form Glutamate. Simultaneously converting NADH to NAD resulting in a decrease in absorbance at 340 nm.



SPECIMEN COLLECTION:

Serum without hemolysis.
Heparinised, EDTA or Oxalated plasma.

KIT PRESENTATION:

Pack Size	2 X 25 ml	3 X 50 ml	5 X 100 ml
R1-Urea (Enzyme Reagent)	2 X 20 ml	3 X 40 ml	4 X 100 ml
R2-Urea (Starter Reagent)	2 X 05 ml	3 X 10 ml	2 X 52 ml
Urea Std. (40mg/dl)	1 X 02 ml	1 X 02 ml	1 X 02 ml

WORKING REAGENT PREPARATION:

Mixing 4 volumes of R1-Urea (Enzyme Reagent) with 1 volume of R2-Urea (Starter Reagent), i.e. 800 μ l R1 + 200 μ l R2.
The working reagent is stable for 30 days at 2-8°C.

REAGENT STORAGE & STABILITY:

All reagents included in the kit are stable at 2-8°C until the expiry date stated on the label.

ASSAY PARAMETERS:

Reaction	: Fix Time	Sample Volume	: 10 μ l
Wavelength	: 340 nm	R1 + R2 Volume	: 800 μ l + 200 μ l
Flow Cell Temp.	: 37°C	Std Conc.	: 40 mg/dl
Initial Delay	: 30 Sec	Reaction Slope	: Decreasing
Interval Time	: 60 Sec	Zero Setting	: Dist. Water
Read Time	: 60 Sec	Linearity	: 300 mg/dl
No. of Reading	: 01	Unit	: mg/dl

PROCEDURE:

Pipette into TT	Standard	Test
R1 - Urea (Enzyme Reagent)	800 μ l	800 μ l
R2 - Urea (Starter Reagent)	200 μ l	200 μ l
Urea Std (40mg/dl)	10 μ l	--
Sample (Test)	--	10 μ l

Mix & aspirate immediately and read difference in absorbance between 30 seconds (AT₁) and 90 seconds (AT₂) for Standard and Test at 340 nm.

CALCULATION:

$$\text{Urea (mg/dl)} = \frac{\Delta\text{Abs of Test} \times \text{Standard Conc.}}{\Delta\text{Abs of Standard}}$$

$$\text{Where } \Delta\text{Abs} = (\text{AT}_1) - (\text{AT}_2)$$

$$\text{BUN Concentration (mg/dl)} = 0.467 \times \text{Urea (mg/dl)}$$

$$\text{Urea concentration (mg/dl)} \times 0.167 = \text{Urea (mMol/L)}$$

NORMAL VALUES:

Serum/Plasma Urea : 10 – 45 mg/dl (1.7- 7.5 mMol/L)

Serum/plasma BUN : 5 – 21 mg/dl

Each laboratory should establish its own reference range.

LINEARITY:

The method is linear up to 300 mg/dl. For Urea concentration higher than linearity limit, mix one volume of sample with one volume of 0.9 % saline and repeat the assay. Multiply the results obtained by two.

REFERENCE:

1. CHANEY, A.L. MARBACH, C.P. Clinical Chemistry, 8:130(1962) SEARCY, R.L. REARDON, J.E. FORMAN, J.A.Amer. J.Med. Technol 33.15 (1967)
2. Talke H., Schubert G. E., Klin. Wschr.43, (1965), 174

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Expiry Date



In-Vitro Diagnostics Use



Storage



Mfg. Date



Batch Number



Catalogue Number



See Package Insert