

SAFETY PRECAUTIONS AND WARNINGS :

This reagent is for *In vitro* diagnostic use only.

INTENDED USE :

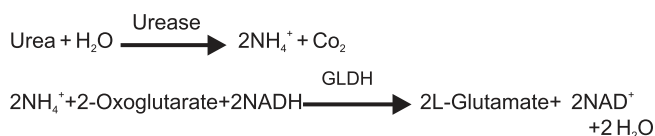
This reagent kit is intended for "*in vitro*" quantitative determination of Urea concentration in serum & urine. Enzymatic (UV) method.

CLINICAL SIGNIFICANCE :

The detoxification of NH_4^+ formed in the catabolism of amino acids takes place in the urea cycle. Enzymes catalyzing these reactions are synthesized in the liver. The end product is Carbamide (Urea) which is a nontoxic, nonpolar, small molecule. It is eliminated by the kidney. Increased levels are associated with renal diseases, as well as dehydration, circulatory collapse, gastrointestinal hemorrhage and diabetic coma. Decreased values are observed in some cases of severe liver disease.

PRINCIPLE :

Ammonia and Carbon dioxide (CO_2) are produced when urea is hydrolyzed in presence of Urease. The Ammonia produced in the reaction combines with 2-Oxoglutarate and NADH in the presence of Glutamate dehydrogenase (GLDH) to yield glutamate and NAD^+ . The NADH/NAD^+ reaction produces a unique change in absorbance at 340 nm, which correlates with the concentration of urea nitrogen in the sample.



REAGENT COMPOSITION :

Reagent 1 : Buffer reagent
Reagent 2 : Enzyme reagent
Urea standard: 50 mg/dl

MATERIALS REQUIRED BUT NOT PROVIDED :

- Clean & Dry Glassware.
- Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

SAMPLES :

Serum free of haemolysis.
Urine diluted in ratio of 1:100 with distilled water. Do not use Anticoagulants containing fluoride or ammonium ions.

STABILITY OF REAGENT :

When Stored tightly closed at 2 to 8°C temperature protected from light and contaminations prevented during their use; reagents are stable up to the expiry date stated on the label.

Avoid direct exposure to light.

WORKING REAGENT :

Mix 4 part of Buffer reagent with 1 part of Enzyme reagent. The working reagent is stable for 30 days at 2 - 8°C.

GENERAL SYSTEM PARAMETERS :

Reaction type	Fixed Time (Decreasing)
Wave length	340 nm
Light Path	1 Cm
Reaction Temperature	37°C
Blank / Zero Setting	Distilled Water
Reagent Volume	1ml
Sample Volume	10 µl
Delay / Lag Time	30 Seconds
Read Time	60 Seconds
Read Interval	60 Seconds
Standard Concentration	50 mg/dl
Low Normal	15 mg/dl
High Normal	45 mg/dl
Linearity	300 mg/dl

ASSAY PROCEDURE :

	Standard	Sample
Reagent	1ml	1ml
Standard	10 µl	
Sample		10 µl

Mix well and after 30 secs incubation read initial absorbance A1.

Exactly after 60 seconds interval read absorbance A2.

Determine the Δ Absorbance.

$$\Delta \text{Abs.} = \text{A2} - \text{A1}$$

CALCULATION :

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

LINEARITY :

Reagent is Linear up to 300 mg/dl.
Dilute the sample appropriately and re-assay if Urea concentration exceeds 300 mg/dl. Multiply result with dilution factor.

REFERENCE NORMAL VALUE :

Serum, plasma : 15-45 mg/dl
Urine : 20-35 g/24h

QUALITY CONTROL :

For accuracy it is necessary to run known controls with every assay.

LIMITATION & PRECAUTIONS :

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assay bring all the reagents to room temperature.
4. Avoid contamination of the reagent during assay process.
5. Do not use the reagent if it is hazy or cloudy.

BIBLIOGRAPHY :

Teitz.N.W.; Fundamentals of clinical chemistry, Philadelphia, W.B. Saunders & Co., Philadelphia, PA, P991 (1976)., Talke H, Schubert GE, Klin Wchrs., (1965), 43, 174.

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