UREA UV

(GLDH Method)

Liquid Reagent

INTENDED USE:

This reagent kit is used for *in-vitro* quantitative determination of Urea in human serum, plasma or urine.

TEST PRINCIPLE:

Following an initial lag phase, the rate of the reaction is constant for 60 seconds. Decrease in absorbance, resulting from the GLDH-reaction, is proportional to the concentration of Urea in the sample.

REACTION :

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

$$NH_3 + \alpha\text{-Ketoglutarate} + NADH \xrightarrow{\text{GLDH}} \text{L-Glutamate} + NAD^+ + H_2O$$

KIT CONTENTS:

Reagent 1: Urea Enzyme Reagent

Reagent 2: Urea Substrate Reagent

Reagent 3: Urea Standard (50 mg/dl)

Product Insert : 01 No.

PREPARATION OF THE WORKING REAGENT:

Mix 4 parts of reagent 1 with 1 part of reagent 2.

REAGENT STABILITY AND STORAGE: 2°C - 8°C.

Unopened kit is stable till expiry date mentioned on the kit when stored at 2-8°C, do not freeze the reagent.

WORKING REAGENT:

Working Reagent is stable for 4 week at 2-8°C & 5 days at 21-25°C

Minimum allowable absorbance of the working reagent measured at 340 nm against water as reference is 1.0.

SAMPLE COLLECTION AND STORAGE:

Do not use Ammonium Heparin Plasma.

Serum/Plasma is stable for 3 days at 21-25°C, 7 days at 2-8°C & 1 Year at -20°C.

Urine is stable for 2 days at 21-25°C, 7 days at 2-8°C & 1 month at -20°C.

Urine diluted 1 ml to 100 ml in distilled water and apply the dilution factor to calculate the final result.

Discard contaminated specimens.

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 assy bring all the reagents to room temperature.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.
7. Reagent ratio as mentioned here above must be strictly observed as may change into it will adversly effect the factor.

PROCEDURE (Automated):

Refer to specific instrument application instructions.

TEST PROCEDURE (Manual):

Wavelength : 340 nm & Temperature : 37°C

Note : Bring reagents and samples to room temperature (21-25°C)

Pipette into Test Tube	Standard	Test
Working Reagent	1.0 ml	1.0 ml
Standard	10 µl	-
Sample	-	10 µl
Mix and record the change in absorbance of the test (ΔA_T) and standard (ΔA_S) between 30 seconds and 90 seconds.		

CALCULATIONS:

$$\text{Serum/Plasma Urea Conc. (mg/dl)} = \frac{\Delta A_T}{\Delta A_S} \times \text{Standard Conc.}$$

Blood Urea Nitrogen (BUN) Conc. (mg/dl) =

0.467 X urea Conc. (mg/dl)

To convert urea conc. (mg/dl) to mmol/l

mmol/l = 0.167 X urea conc. in mg/dl

NORMAL VALUES*:

Serum/Plasma Urea : 10 to 40 mg/dl

Urine : 26 to 43g/24hrs.

*It is recommended that each laboratory should establish its own normal range.

PERFORMANCE:

1. **Linearity:** 300 mg/dl
2. **Comparison:** r = 0.98

   y = 0.097 x +0.55
3. **Precision:**

	Within Run			Run to Run		
	Mean	**S.D.**	**C.V.%**	**Mean**	**S.D.**	**C.V.%**
Low	14.4	0.4	2.5	14.0	0.9	2.5
High	55.0	1.8	2.6	55.0	1.8	2.5

4. **Specificity:**

   Do not use ammounium heparin as Anticoagulants improperly cleaned glassware may inhibit urea activity. The method is relatively free of interference from commonly used drugs and other body metabolites.

CLINICAL SIGNIFICANCE:

Urea is the major end product of protein metabolism. Impaired renal function (viz, glomerulonephritis, pyelonephritis etc.) is associated with elevated levels of urea. Increased levels of urea are also found during severe dehydration and massive gastrointestinal bleeding. Decreased levels are associated with liver damage and pregnancy.

AUTOMATED APPLICATIONS:

UREA UV Liquid Reagents can be used with most of the commonly available semi-auto and fully- automated biochemistry analyzers. Application sheets for use on specific semi-automatic, batch analyzers are available on request.

Input parameters for semi-auto/auto analyzers are given below.

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Decreasing
Wavelength	340 nm
Standard concentration	50 mg/dl
Incubation time	30 sec.
Interval time	60 sec.
Interval No.	1
Flowcell temperature	37^{o}C
Units	mg/dl
Upper Normal value	40 mg/dl
Lower Normal value	10 mg/dl
Linearity	300 mg/dl
Working Reagent volume	1.0 ml
Sample / Standard volume	10 µl

QUALITY CONTROL:

For accuracy, it is necessary to run known serum controls with each assay.

REFERENCES:

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-BooksVerlagsgesellschaft; 1998. p. 374-7.
2. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company: 1999. p. 1838.
3. Taike H, Schubert GE. Enzymatische Hamstoffbestimmung in Blut und Serum im optischen Test nach Warburg (Enzymatic determination of urea in blood and serum with the optical test according to Warburg). Klin Wschr 1965; 43:174-5.

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