UREA - GLDH

METHOD – UV-KINETIC
PRODUCT CODE – LU02

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Urea GLDH activity in serum / plasma using UV-Kinetic method.

SUMMARY AND PRINCIPLE

Increased Urea / Urea Nitrogen levels are associated with renal diseases, as well as dehydration, gastrointestinal haemorrhage and diabetic coma. Decreased values are observed in some cases of severe liver disease. Urea - GLDH is a reagent set for quantitative determination of Urea or Urea Nitrogen in human serum / plasma based on enzymatic UV-kinetic initial rate method, using urease and glutamate dehydrogenase.

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

$$NH_3 + \alpha\text{-ketogluterate} + \text{NADH} \xrightarrow{\text{GLDH}} \text{Glutamate} + NAD^+$$

KIT COMPONENTS

Reagent 1: Reagent 1
Reagent 2: Reagent 2
Reagent 3: Urea Standard (50 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Reagent R1 and R2 are ready to use liquid reagent. Mix reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired volume of working reagent. The reagent kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label. Urea high cal is ready to use.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent goes below 1.000 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Urea GLDH
Reaction Type	UV-Kinetic (↓)
Wavelength	340 nm
Flow Cell Temp.	37 °C
Blank setting	D.W.
Blank abs. limit	> 1.000
Linearity	535 mg/dL

Reagent Volume	1000 µl
Sample Volume	10 µl
Temperature	37 °C
Delay Time	30 sec.
Read Time	60 sec.
Standard Conc.	50 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container (free of NH_4^+). Ammonium salt of anticoagulants and sodium fluoride should not be used as anticoagulant. Heparinized or EDTA plasma can be used. Urea in the specimen is stable for a week when stored at 2-8 °C and for 6 months when stored at -10 °C.

COMPONENTS OF REAGENT

Component	Concentration
Tris Buffer, pH 7.7	50 mmol/L
Urease	10 KU/L
GLDH	900 IU/L
α-ketogluterate	10 mmol/L
NADH	0.25 mmol/L
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Standard	Test
Reagent	1000 µl	1000 µl
Standard	10 µl	NA
Sample	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio and start the stop watch.		
Aspirate reaction mixture into flow cell and measure the absorbance at 30th and 90th sec.		

CALCULATION

$$\text{Urea (mg/dL)} = \frac{\text{Abs. of sample} \times 50}{\text{Abs. of standard}}$$

$$\text{Urea Nitrogen (mg/dL)} = \frac{\text{Urea (mg/dL)}}{2.14}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Urea: 17 - 49 mg/dL.
Urea Nitrogen: 8 - 23 mg/dL.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 5 - 535 mg/dL. If the Urea value exceeds linearity limit (above 535 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Urea value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	30.31	1.16	3.8	35.36	0.73	2.1
High Value Serum	104.7	1.49	1.4	0.1	0.00	1.8

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Urea. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance is < 1.000 at 340 nm against distilled water.

2. Fluoride as an anticoagulant cannot be used as it inhibits Urease activity. Anticoagulant having ammonium ions should not be used as they give false high result.

3. If the Urea value exceeds 535 mg/dL then dilute the specimen suitably with normal saline and repeat the assay. In such case multiply the results obtained with the dilution factor to obtain correct Urea value.

4. Do not use strongly hemolysed sample.

BIBLIOGRAPHY

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Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE