

Urea UV Test kit

REF	Pack Size	Reagent 1	Reagent 2	Reagent 3 (Std)
URULMS01	2x25 ml	2x20 ml	2x5 ml	1x2 ml
URULMS02	2x50 ml	2x40 ml	2x10 ml	1x2 ml

INTENDED USE

Urea UV reagent used for the quantitative determination of urea in human serum.

CLINICAL SIGNIFICANCE

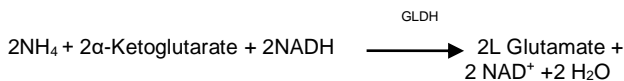
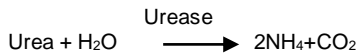
Urea is the nitrogen containing product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyper uremia or azotemia. Parallel determination of urea and creatinine is performed to differentiate between pre-renal and post-renal azotemia. Pre-renal azotemia caused by e.g. dehydration increases protein catabolism, cortisol treatment or decreased renal perfusion leads to increase urea levels, while creatinine values remain within the reference range. In post-renal azotemia e.g. caused by the obstruction of urinary tract, both urea and creatinine levels rise but creatinine in a smaller extent. In renal diseases urea concentrations are elevated when the glomerular filtration rate is markedly reduced and when the protein intake is higher than 200g/day.

METHOD: UV Kinetic – GLDH Method

TEST PRINCIPLE

Urease hydrolyzes urea to ammonia and CO₂. The ammonia formed further combines with ketoglutarate and NADH to form glutamate and NAD. The rate of oxidation of NADH to NAD is measured as a decrease in absorbance in a fixed time, which is proportional to the urea concentration in the sample.

REACTION



GLDH=Glutamate dehydrogenase.

KIT CONTENTS/COMPONENT

- Reagent 1: (Urea Enzymes)
- Reagent 2: (Substrate)
- Reagent 3: Standard (40mg/dl)

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE AND STABILITY

Working Reagent: R1=800 µl and R2= 200 µl
 Mix 4 volume of Reagent 1 and 1 volume of Reagent 2 to make desired volume Working reagent. Working reagent is stable for 5 days at 20-25°C and for 30 days at 2-8°C.
 When stored at 2-8°C and protected from light, the unopened kit reagents are stable until the expiry date stated on the label.

SAFETY PRECAUTIONS & Warnings

- For in-vitro diagnostics use only.
- Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
- Do not use the reagent after the expiration date printed on the kit.

REAGENT DETERIORATION

Discard the reagent if absorbance less than 1.0 at 340nm against distilled Water.

PROGRAM

Reaction Mode	Fixed time
Wavelength	340 nm
Light Path	10 mm
Reagent Volume	1000 µl
Sample Volume	10 µl

Delay Time	30 sec
Read Time	90 sec
Standard Concentration	40 mg / dl
Linearity	300 mg / dl

PROCEDURE

Addition Sequence		
Reagent	1000 µl	1000 µl
Standard	10 µl	-----
Sample	-----	10 µl

Mix well and read the initial absorbance A1 for the standard and test after exactly 30 second, read another absorbance A2 of the standard and test exactly 90 sec. at 340nm.

CALCULATION

$$\text{Urea (mg/dl)} = \frac{\Delta\text{AT}}{\Delta\text{AS}} \times 40\text{mg/dl (Conc of std)}$$

NORMAL VALUE

Serum, plasma: 15-50 mg/dL

Each laboratory should establish its own normal range representing its patient population.

LIMITATIONS

If the value exceeds 300mg/dl dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (Bio Norm) and assayed abnormal (Biopath), to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator (Bio Cal) or the Standard included, calibrate the assay.

- When using a new reagent or lot
- When QC values are out of range

WASTE DISPOSAL










This Product is made to be used in professional laboratories.

HIGHLIGHT

- The Reagents are sensitive to light & higher temperature. Reagents may develop a slight pink coloration on ageing which does not interfere with the functionality of reagent.
- If the volume of the reagent is not sufficient to fill the cuvette, double all the specified volumes.
- Storage condition mentioned on the kit is to be used.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Before testing bring the reagents to the RT.
- Avoid reagents contamination.
- Every time use new pipette-tips for pipetting out the reagents.
- These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCE

Tietz N.W., ed. Clinical Guide to laboratory Tests, 3rd ed. Philadelphia, Pa: W.B. Saunders, 622 – 626.
 Lords Data File.

 REF	Catalog No.		Contain Sufficient for test
 LOT	Batch No.		Instruction for use
	Manufacturing Date		In-vitro Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/URU/01 Rev.: 02; Rev Dated.: 22/07/2024

