Urea UV Test kit

REF	Pack Size	Reagent 1	Reagent 2
URULMB01	1 x 60 + 1 x 15	1 x 60ml	1 x 15ml

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 in 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 CO_2. 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
$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_4 + CO_2$$

$$2NH_4 + 2\alpha\text{-Ketoglutarate} + 2NADH \xrightarrow{\text{GLDH}} 2L\ \text{Glutamate} + 2\ NAD^+ + 2\ H_2O$$

GLDH=Glutamate dehydrogenase.

KIT CONTENTS/COMPONENT
Reagent 1: (Urea Enzymes)
Reagent 2: (Substrate)

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

REAGENT PREPARATION, STORAGE AND STABILITY
Reagent is ready to use & are stable up to expiry date mentioned on the pack.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

Specimen
Serum/plasma is stable for 7 days at 2-8°C, or one month at -20 °C.

APPLICATION For LM1016-400 TPH

Method	Two points
Primary filter	340
Secondary filter	No
R1 Volume	240
R1 Position	*
Incubation time (Sec)	120
R2 Volume	60
R2 Position	*
Incubation time (Sec)	30
Sample Volume	3
Read Time	90
Calibrator Concentration	As on vial label
Mix speed set	Middle
Unit	mg/dl
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Urea concentration of each sample.

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.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result. Using the recommended multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dl)	31.48	95.6	31.48	95.65
SD	1.24	1.42	1.24	1.42
CV (%)	0.039	0.015	0.039	0.015

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturing Date		Storage temperature
	Expiry Date		Manufacturer

IFU/URU/03 Rev.: 00; Rev Date.: 22/07/2024

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