AGD
CliniPak

UREA UV

(UV - KINETIC)

Code	Pack Size
AGDSP - UR125	R1 : 5 X 20 mL R2 : 5 X 5 mL
AGDSP - UR115	R1 : 5 x 18mL R2 : 5 x 5mL
AGDSP - UR145	R1 : 5 x 23mL R2 : 5 x 6mL

INTENDED USE

Urea is a reagent set for in vitro quantitative determination of Urea in serum, plasma or urine.

CLINICAL SIGNIFICANCE

Urea is the main end product of protein catabolism. Deamination of amino acids takes place in the liver whereby the ammonia released is converted into urea.

Increased Levels : are observed in renal diseases,dehydration, shock, acute glomerulonephritis, urine retention, gastrointestinal hemorrhage and diabetic coma.

Decreased Levels : are observed in severe liver diseases

PRINCIPLE

In presence of Urease and water, Urea hydrolyses to produce Ammonia and Carbon dioxide.The Ammonia produced in the reaction combines with 2-Oxoglutarate and NADH in the presence of Glutamate dehydrogenase to yield glutamate and NAD+ The NADH /NAD+ change in absorbance at 340nm, which correlates with the concentration of urea nitrogen in the sample. Reaction produces a unique change in absorbance at 340nm, which correlates with the concentration of urea nitrogen in the sample.

$$\text{Urea} + H_2O \xrightarrow{\text{UREASE}} 2NH_4^+ + CO_2$$

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

PROCEDURE

Reagent 1 + Incubation + Sample

(240µL) (60 secs) (3µL)

Reagent 2 ⟶ Measurement

(60µL) (90 secs) (340 nm)

REAGENT COMPOSITION

REAGENT 1

Buffer (pH 7.4)	≈ 80 mmol/L
α-Keto Glutarate	≈ 6 mmol/L
Urease	> 35000 mmol/L

REAGENT 2

NADH	≈ 0.32 mmol/L
Preservatives, Stabilizers	≈ Q. S.

REAGENT STORAGE AND STABILITY

Urea is a two reagent system ready to use.

The reagent is stable till the expiry date stated on the reagent bottle label when stored at 2-8°C protected from light.

SAMPLE

Collected sample using standard sampling tube preferably serum samples can be used. Heparinised plasma or EDTA plasma can be used.Do not use hemolysed or grossly contaminated samples.

BASIC PARAMETER

SHORT NAME	UREA
NAME	UREA
METHOD	UV-KINETIC
ASSAY	Fixed time/Two Point
MAIN WAVE	340 nm
SUB WAVE	0
DECIMAL	2
UNIT	mg/dL
R1 VOLUME	240 µL
INCUBATION	60secs
R2 VOLUME	60 µL
SAMPLE VOLUME	3µL
INCUBATION	0
MIXING SPEED	0
REACTION TIME (DELAY)	30 secs
CHECK TIME (READ)	60 secs
LINEAR RANGE	0-300
ABSORBANCE RANGE	0-2.5
LINEARITY LIMIT	30
SUBSTRATE SHORTAGE	< 0.7
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

Enter calibrator value as per the lot of calibrator and method.

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.

PRECISION

Reproducibility of within run, determined using quality control sera as shown below.n=15

Quality control material	Mean mg/dL	SD mg/dL	% CV
Low Control serum	44.9	0.86	1.93
High Control serum	117	0.37	0.31

REFERENCE NORMAL VALUE

Serum / Plasma : 15 - 45 mg/dL Urine: 20 - 35 g/24h

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

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