UREA UV SL

Kinetic Method UV

Ready-to-use liquid reagents

REF 12400160 R1 8X20mL
REF 12410040 R2 8X5mL

IVD

PRODUCT CODE: URE-8D25

Company with Quality System ISO 9001 – ISO 13485Certified by LMS

INTENDED USE

Quantitative determination of urea in serum, plasma and urine.
Urease - GLDH Method.

PRINCIPLE

Urea, in the presence of urease, is hydrolyzed to ammonium ion and carbon dioxide. In the presence of glutamate-dehydrogenase (GLDH), the formed ammonium ion reacts with α-ketoglutarate and NADH to form glutamate and NAD+. Measured at 340 nm, NADH oxidation in unit time is proportional to the urea concentration in the sample.

SAMPLE

Serum, plasma with heparin, urine.
Avoid anticoagulants containing ammonium salts and fluoride.
The urine should be diluted 1:100 with saline.
Urea in the sample is stable 3 days at 2-8 °C.

KIT COMPONENTS

Reagent (A) Volume = 40/80 ml	Good Buffer ADP α-ketoglutarate Urease GLDH	100 mmol/l 1 mmol/l 9 mmol/l 8100 U/l 1350 U/l
Reagent (B) Volume = 10/40/80 ml	NADH	1.5 mmol/l
Standard Volume = 10 ml	Urea	**Value on label**

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C. Do not use over expiry date.
Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Keep bottles closed when not in use.

REAGENT PREPARATION

Liquid Reagent, bring to room temperature (15-25°C) before use.
For **use as monoreagent**: add a part of Reagent (B) to 4 parts of Reagent (A).
The working solution (A+B) is stable 3 weeks in refrigerator (2-8 °C).

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	340 nm (334 – 365)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	Decreasing kinetic

Use as monoreagent:

pipette:	**blank**	**sample**	**standard**
Reagent (A+B)	300 µl	300 µl	300 µl
water	5 µl		
sample		5 µl	
standard			5 µl

Use as bireagent (starter sample)
Kinetic or Fixed Time Method:

pipette:	**blank**	**sample**	**standard**
Reagent (A)	240 µl	240 µl	240 µl
Reagent (B)	60 µl	60 µl	60 µl
Mix, wait 30 seconds, then add:			
water	5 µl		
sample		5 µl	
standard			5 µl

Mix and after 30 seconds of incubation at 37°C, read against water the initial absorbance. Read again after exactly 60 seconds. Calculate the variation value of the absorbance of the sample and the standard.

RESULTS CALCULATION

Serum/plasma:
Urea mg/dl = ΔAx/ΔAs x 50 (standard value)

Urine:
Urea mg/dl = ΔAx/ΔAs x 50 x 100 (dilution)

24 hours Urine:

$$\text{Urea g/24h} = \frac{\Delta Ax/\Delta As \times 50 \times 100 \times \text{Urine Volume (dl)}}{1000}$$

EXPECTED VALUES

Serum/plasma

UREA: 13 - 45 mg/dl (2.1 - 7.5 mmol/l)
GOOD: 6 - 21 mg/dl

24h Urine

UREA: 26 – 43 g/24h (428 - 714 mmol/24 h)

Each laboratory should establish appropriate reference intervals related to its population.

CONVERSION FACTORS

Urea [mg/dl] x 0.1665 = Urea [mmol/l]
BUN (Blood urea nitrogen)[mg/dl] x 2.14 = Urea [mg/dl]
Urea [mg/dl] x 0.467 = BUN [mg/dl]
BUN [mmol/l] x 2.801 = BUN [mg/dl]

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 1 mg/dl.
Linearity: the method is linear up to 300 mg/dl. For higher values, dilute the sample 1:10 with saline and multiply the result by 10.
Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	27.28	54.85	147.2
SD	0.893	0.994	1.229
CV %	3.27	1.81	0.84

Precision inter-assay:

	Level1	Level 2	Level 3
Mean (mg/dl)	28.00	54.56	151.5
SD	0.450	0.669	1.354
CV %	1.61	1.23	0.90

Interferences: bilirubin and ascorbic acid do not interfere up to 30 mg/dl. Triglycerides do not interfere up to 1000 mg/dl. Hemoglobin does not interfere up to 500 mg/dl.
Correlation against a reference method:
Y = 1.0126x + 1.218 r = 0.9998

REFERENCES

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3. Vassault A. et al., Ann. Biol. Clin., 44, 686 (1986).

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