UREA UV SL

Kinetic Method UV

Reagenti liquidi pronti all'uso

REF. 4164/50 4x 50 ml
REF. 4164/B 8x 50 ml
REF. 4164 4x100 ml
REF. 4170 2x100 ml

CE
IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of urea in serum, plasma and urine.
GLDH - Urease 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 h eparin, 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	50 mg/dl (8.325 mmol/l)

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C. 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 5 days at room temperature (15-25°C) and 4 weeks in refrigerator.

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)	1000 µl	1000 µl	1000 µl
water	10 µl		
sample		10 µl	
standard			10 µl

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

pipette:	blank	sample	standard
Reagent (A)	1000 µl	1000 µl	1000 µl
Reagent (B)	250 µl	250 µl	250 µl
Mix, wait 30 seconds, then add:			
water	10 µl		
sample		10 µl	
standard			10 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.

Reaction volumes can be proportionally varied.
This method describes the manual procedure to use the kit.
For automated procedure, ask for specific applications.

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:	**10 – 50**	**mg/dl**	**(1.7 – 8.3 mmol/l)**
Urine :	**847 – 2967**	**mg/dl**	**(141 – 494 mmol/l)**
24h Urine:	**10 – 35**	**g/24h**	**(170 – 580 mmol/24h)**

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

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 control sera: PRECISENORM (REF.6000) and PRECISEPATH (REF.6001).

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 and multiply the result by 10.
Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	27.28	54.85	147.2
DS	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
DS	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

1. Krieg M. et al., J Clin Chem Clin Biochem 1986; 24:863.
2. Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989.
3. Vassault A. et al., Ann. Biol. Clin., 44, 686 (1986).

Giesse Diagnostics srl
Via Cervinara, 45 – Colle Prenestino – Roma – Italia. Tel. +39 06 22429353 / +39 06 22429097 – Fax +39 06 22429098
e-mail: info@giessediagnostics.com – web site: www.giessediagnostics.com

416407
Ed. 2012/03 rev. 00