Biomaghreb

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CE

UREA

Kinetic Test U.V

Reagent for the quantitative determination of urea in human plasma and urine.

IN VITRO DIAGNOSTIC USE

IVD

REF	**31013**	**4 x 50 ml** (200 T)	**R1:** 4 x 50 ml	**R2:** 4 lyophilisates	**R3:** 1 x 4 ml
REF	**31020**	**9 x 50 ml** (400 T)	**R1:** 9 x 50ml	**R2:**9 lyophilisates	**R3:** 2 x 5 ml

CLINICAL SIGNIFICANCE

Urea is a molecule resulting from the process of protein catabolism, eliminated by the kidneys in the form of nitrogenous waste products.
Determination of urea levels therefore makes it possible to assess renal function, particularly in diabetics and patients who have suffered a myocardial infarction. In the case of renal dysfunction, there is an increase in uremia. In addition, certain liver diseases can also alter the level of urea in the blood. The urea dosage alone is not very informative, since the urea produced each day varies according to diet, age and hydration status. For this reason, creatinine and uric acid determinations are usually done at the same time. In addition, the determination of urea clearance is used to evaluate the filtration rate of the kidneys and the efficiency of dialysis.

PRINCIPLE

Enzymatic method based on the reaction principle described by Talke and Schubert :
The decrease in absorbance following the conversion of NADH to NAD+ at 340 nm is proportional to the concentration of urea in the sample.

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

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

GLDH : *Glutamate dehydrogenase*

REAGENT COMPOSITION

Reagent 1 Buffer solution	Buffer Tris pH 8	80 mmol/l
Reagent 2 Enzymes	Urease GLDH NADH Oxo-2-glutarate	>10 000U/l 16 000 U/l 0.30 mmol/l 15 mmol/l
Reagent 3 Standard	Standard Urea	50 mg/dl 8.325 mmol/l

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use (do not pipette by mouth).

- Refer to the current SDS available on request or at www.biomaghreb.com;
- Verify the integrity of the reagents before use; and
- Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious.
Respect the legislation in force.

REAGENT PREPARATION

Working solution :
Dissolve a vial of R2 in a vial of R1.

SAMPLE PREPARATION

Serum, plasma collected on heparin.
Urine diluted 1:100 with distilled water.

PRESERVATION AND STABILITE

- Before opening : Until the expiry date indicated on the label of the box at 2-8°C;
- After opening : (working solution) :
  5 days at 20 -25°C ;
  3 weeks at 2-8°C.

ADDITIONAL EQUIPMENT

- Basic equipment of the medical analysis laboratory ;
- Spectrophotometer or Clinical Biochemistry Analyzer.

LIMITS

Do not use anticoagulants containing fluoride or ammonium ions.

QUALITY CONTROL

External quality control program.
It is recommended to control in the following cases:

- At least one test per series.
- Change of reagent bottle.
- After maintenance work on the analyzer.

If a control value is outside the confidence limits, repeat the procedure using the same control.
Use normal and pathological control sera.

CALIBRATION

The standard of the kit (Reagent 3) or any calibrator connected to a method or reference material.
The frequency of calibration depends on analyzer performance and reagent storage conditions.
Recalibration is recommended in the following cases:

1. Changing the reagent lot;
2. After maintenance work on the analyzer; and
3. Control values are outside the confidence limits.

LINEARITY

The method is linear up to 2 g/l (200 mg/dl - 33.3mmol/l).

PROCEDURE

Wavelength: 340 nm ;
Temperature : 25-30-37°C ;
Tank : 1 cm thick;
Adjust the spectrophotometer zero to air or distilled water.

	Standard	**Sample**
Working solution	1 ml	1 ml
Preincubate at selected temperature 25, 30, 37°C		
Reagent 3	10 µl	--
Sample	--	10 µl
Mix, measure the decrease in OD between : t = 20 secondes and t = 80 secondes.		

CALCULATION

$$\text{Urea} = \frac{\Delta \text{ OD Sample}}{\Delta \text{ OD Standard}} \times n \qquad n = \text{Standard value}$$

n = 50 mg/dl;
n = 0, 5 g/l;
n = 8,325 mmol/l.

REFERENCE VALUES

Serum or plasma	15 - 40 mg/dl 0,15 – 0,40 g/l 2,49 – 6,66 mmol/l
Urine	20 - 35 g/24 h

REFERENCES

Talke H, Schubert GE 1965. Klin Wochenschr 43:174-5 ;
Chaney, A. Clin. 8, 130 (1962) ;
Fawcett J.K., J. Clin. Path.13, 15 (1960).

Manufacturer | Use by | In Vitro Diagnostic | Temperature Limitation | Catalogue number | See insert | Store away from light | Sufficient for < n > essais | Batch number