Biomaghreb

6, Rue Ibn Ennafis - Z.I. Lac 3 Tunisie
Tél. : 71 182 500 - Fax : 71 182 250
www.biomaghreb.com

CE

CREATININE

Colorimetric kinetic method without deproteinization

Reagent for the quantitative determination of creatinine in human plasma and urine

IN VITRO DIAGNOSTIC USE

IVD

REF	**25012**	**2 x 160 ml** (320 T)	**R1:** 2 x 80 ml	**R2:** 2 x 80 ml	**R3:** 1 x 15 ml
REF	**25029**	**2 x 500 ml** (1000 T)	**R1:** 1 x 500 ml	**R2:** 1 x 500 ml	**R3:** 2 x 25 ml
REF	**25036**	**1 x 500 ml** (500 T)	**R1:** 1 x 250 ml	**R2:** 1 x 250 ml	**R3:** 1 x 25 ml
REF	**25043**	**1 x 160 ml** (160 T)	**R1:** 1 x 80 ml	**R2:** 1 x 80 ml	**R3:** 1 x 8 ml

CLINICAL SIGNIFICANCE

Creatinine is produced after the degradation of creatine (a muscle protein) by kidneys
The creatinine level provides information about the functioning of the kidneys and the muscle mass of the patient. An elevated creatinine level is often a sign of kidney failure. The measurement of its clearance is therefore an indicator of the glomerular filtration rate.
Low creatinine may be a sign of myopathy (severe muscle atrophy)

PRINCIPLE

Creatinine forms a colored complex with picric acid in an alkaline medium. The rate of formation of this complex is proportional to the concentration of creatinine.

REAGENT COMPOSITION

Reagent 1	Sodium Hydroxide	1.6 mmol/l
Reagent 2	Picric Acid	17.5 mmol/l
Reagent 3 Standard	Standard Creatinine	2 mg/dl 20 mg/l 176.8 µmol/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: Mix equal parts R1 and R2.

SAMPLE PREPARATION

Serum, plasma collected on heparin.
Urine diluted 1:20 with distilled water (take the dilution into account for the calculation).

PRESERVATION AND STABILITY

- Before opening: The reagents are ready to use, stable up to the expiry date indicated on the label of the box at 20-25°C;
- After opening (Working Solution) : 1 month at 20 - 25°C.

ADDITIONAL EQUIPMENT

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

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 150 mg/l (15 mg/dl - 1326 µmol/l). If the creatinine concentration is higher than 150 mg/l, dilute the sample 1/2 with 9 g/l NaCl solution and repeat the test. Multiply the result by 2.

PROCEDURE

Wavelength: 492 nm (490 - 510)
Temperature: 25 - 30 or 37 °C
Tank : 1 cm thick.
Adjusting the spectrophotometer zero with air or distilled water.

	Standard	**Sample**
Standard	100 µl	- -
Sample	- -	100 µl
Working solution	1 ml	1 ml

Mix and read OD1 absorbances after 30 seconds.
Then read OD2 exactly 1 minute after.

CALCULATION

Calculate Δ OD = OD2 - OD1 for standard and samples.

$$\text{Creatinine} = \frac{\Delta \text{ OD. Sample}}{\Delta \text{ OD. Standard}} \times n$$

n = Standard value

n = 2 mg/dl ;
n = 20 mg/l ;
n = 176.8 µmol/l

REFERENCE VALUES

Serum or plasma	0.7 - 1.4 mg/dl 7-14 mg/l 61.8 -132.6 µmol/l
Urine	15-25 mg/kg/24h

REFERENCES

Henry J.B., Clinical Diagnosis and management 17th édition, Sauders Publisher 1984.
Larsen K., Clin. Chim. Acta 66, 209 (1972).

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