CREATININE

Kinetic modified Jaffè method

Liquid Reagents ready to use

REF. 0060/50 4x 50 ml
REF. 0060/2 2x100 ml
REF. 0060 4x100 ml
REF. 0062 4x250 ml

CE IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of creatinine in serum, plasma and urine.

PRINCIPLE

Creatinine reacts in an alkaline environment with picric acid forming a salt of a yellow-orange color. The intensity of the color that develops in a predetermined time interval is proportional to the amount of creatinine in the sample.

SAMPLE

Serum, plasma with heparin, urine 24h, diluted 1:100 with saline.
Do not use hemolyzed samples.
Creatinine in the samples is stable 24 hours at 2-8°C.
Freeze the sample for longer periods.

KIT COMPONENTS

Reagent (A) CREA Volume = 50/100/250 ml	Picric Acid	29 mmol/l
Reagent (B) CREA Volume = 50/100/250 ml	Buffer Sodium hydroxide	100 mmol/l 600 mmol/l
Standard Volume = 10 ml	Creatinine derivative (**Value in label**)	

The reagents are stable until the expiration date indicated on the label if stored at 15-25°C and protected from light. Do not freeze. Once opened reagents are stable for 2 months at 15-25°C if contamination is avoided.
Keep bottles closed when not in use, **especially the Reagent (B).**

REAGENT PREPARATION

Mix the Reagents (A) and (B) into equal parts. Stabilize the working solution 15 minutes before use. Use the necessary quantities depending on the number of analyzes to be carried.
The working solution is stable for 7 days at room temperature.

PRECAUTIONS AND WARNINGS

The Reagent (B) contains sodium hydroxyde and, according to current regulation, is classified as: **C – Corrosive. R34 –** Causes burns. **S26** – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. **S45 –** In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). **S36/37/39** – Wear suitable protective clothing, gloves and eye/face protection. A safety data sheet is available on request.
Reagents 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:	492 nm (490 – 510)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	Increasing Kinetic
Sample/Reagent:	1/10

pipette:	**sample**	**standard**
Reagent (A +B)	1000 µl	1000 µl
sample	100 µl	
standard		100 µl

Mix, incubate at 37°C for 30 seconds, and read the absorbance of the sample (Ax1) and standard (As1). After exactly one minute from the first reading, read the absorbance of the sample (Ax2) and standard (As2).

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

RESULTS CALCULATIONS

Serum/plasma:

Creatinine mg/dl = (Ax2 - Ax1) / (As2 - As1) x Standard Value

Urine 24h: **Creatinine mg/24h =**
= (Ax2 - Ax1)/(As2 - As1) x Std Value x 100 (dilution) x diuresis (in dl)

Clearance creatinine (ml/min)=creatinine urine (mg/dl) x [diuresis (ml)/1440]
Creatinine serum (mg/dl)

EXPECTED VALUES

Serum, plasma:

Men: 0.7 – 1.2 mg/dl (62 – 106 µmol/l)
Women : 0.6 – 1.1 mg/dl (53 – 97 µmol/l)

Urine: **1 – 1.5 g/24h (8.8 – 13.3 mmol/l)**

Clearance:

Men: 98 – 160 ml/min
Women : 95 – 150 ml/min

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: 0.1 mg/dl.
Linearity: the method is linear up to 30 mg/dl. For higher values, dilute the sample 1:2 and multiply the result by 2.
Precision intra-assay:

	Level 1	Level 2
Mean (mg/dl)	1.22	3.76
DS	0.012	0.017
CV %	1.01	0.46

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	1.25	3.81
DS	0.011	0.021
CV %	0.85	0.54

Interferences: Ascorbic acid up to 100 mg/dl does not interfere. bilirubin does not interfere up to 5 mg/dl. A hemoglobin concentration greater than 100 mg/dl increases the reading. Glucose up to 500 mg/dl does not interfere.
Correlation against a reference method: Y = 0.9294x + 0.16 r = 0.9998

REFERENCES

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