CREATININE SL

Kinetic modified Jaffè method

Liquid Reagents ready to use

REF. 0066 5x100 ml

IVD CE

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

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 = 4x100 ml	Picric Acid	40 mmol/l
Reagent (B) CREA Volume = 2x50 ml	Buffer Sodium hydroxide	100 mmol/l 500 mmol/l
Standard Volume = 10 ml	Cratinine 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 use over expiry date.

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).**

REAGENTS PREPARATION

Liquid Reagents ready to use.

Use thel Reagent (A) and the Reagent (B) in the ratio: 4+1.

PRECAUTIONS AND WARNINGS

EC Regulament 1272/2008 (CLP):

Reagent (B) :

Warning

H319 Causes serious eye irritation.

H315 Causes skin irritation.

P280 Wear protective gloves / protective clothing/eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P332+P313 If skin irritation occurs: Get medical advice / attention.

Reagents may contain some non-reactive and preservative components. Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	510 nm (490 – 510)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Mehtod:	Increasing Fixed time
Sample/Reagent:	1/10

pipette:	**sample**	**standard**
Reagent (A)	400 µl	400 µl
sample	50 µl	
standard		50 µl

Mix, incubate at 37°C for 1 minute, and read the absorbance of the sample (Ax1) and the standard (As1). Add:

Reagent (B)	100 µl	100 µl

Mix, incubate at 37°C for 30 seconds and after 2 minutes read the absorbance of the sample (Ax2) and the 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 CALCULATION

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)	1.69	4.08
DS	0.04	0.09
CV %	2.55	2.19

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	1.71	4.11
DS	0.05	0.09
CV %	2.70	2.25

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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Giesse Diagnostics srl
V. Enrico Fermi, 3 - Z.I. V. Tiburtina Km 18.300 - 00012 Guidonia Montecelio (RM) - Italia
Tel. +39 0074 051100 - Fax +39 0774 051111
e-mail: info@giessediagnostics.com – web site: www.giessediagnostics.com

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