

CREATININE

Kinetic modified Jaffè method
Liquid Reagents ready to use

REF 13200125 R1 1X125mL
REF 13201125 R2 1X125mL

IVD

PRODUCT CODE: CRE-8D28

INTENDED USE

Quantitative determination of Creatinine in serum, plasma and urine.

CLINICAL SIGNIFICANCE

Creatinine is a byproduct of the breakdown of creatine, and the amount endogenously produced is proportional to an individual's muscle mass; therefore, its production varies with age and sex. The Creatinine produced is released into the blood, and elevated levels may indicate acute or chronic renal failure, or cases of dehydration.

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 = 100/250 ml	Picric Acid	< 20 mmol/l	
Reagent (B) CREA Volume = 100/250 ml	Potassium Hydroxide Tribasic Sodium Phosphate Sodium Azide	< 0.35mmol/l < 92 mmol/l <1 mmol/l	!
Standard Volume = 5 ml	Creatinine derivative	Value on 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).**

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

Reagent (B) – Contains *Tribasic Sodium Phosphate (CAS 10101-89-0)*
Potassium Hydroxide (CAS 1310-58-3)

Signalwords: **Warning**

H319 Causes serious eye irritation.

P337+P313 If eye irritation persists: Get medical advice / attention.

P264 Wash with water thoroughly after handling.

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: 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)	250 µl	250 µl
sample	25 µl	
standard		25 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).



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H315 Causes skin irritation.

P280 Wear protective gloves / eye protection / face protection

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(dl)

Clearance creatinine (ml/min)=

= $\frac{\text{creatinine urine (mg/dl)} \times [\text{diuresis (ml)} / 1440]}{\text{Creatinine serum (mg/dl)}}$

Conversion factor: mg/dl x 88,4 = µmol/l

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)

Children:	1 day	3 months	1 year	2-12 years
mg/dl:	0.6 - 1.2	0.2 - 0.4	0.3 - 0.7	0.35 - 1.0
µmol/l:	53 - 106	18 - 35	0.3 - 27	31 - 88

Urine:

Men: 1000 – 2300 mg/24h (8.8 – 20.35 mmol/24h)
Women: 800 – 1800 mg/24h (7.0 – 15.93 mmol/24h)

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 Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 0.4 mg/dl.

Linearity: the method's linearity was tested up to 24 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
SD	0.012	0.017
CV %	1.01	0.46

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	1.25	3.81
SD	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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- Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989
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