CREATININE

Jaffè method - Fixed time

R1: 2 x 50 ml + R2: 2 x 50 ml CL26-200S
R1: 2 x 100 ml + R2: 2 x 100 ml CL26-400S

INTENDED USE

Kit for quantitative determination of Creatinine in serum and urine.

CLINICAL MEANING

Creatinine is the result of phosphocreatine catabolism and its production is strictly related to the organism's muscular mass. It is entirely eliminated in urine through renal ultra-filtration. If the filtration function of kidneys is regular, creatinine concentration in serum and the quantity eliminated through urine are constant.
In case of renal deterioration, the kidney cannot eliminate the right amount of creatinine in the blood: this leads to an increase in the substance, which doubles at each 50% reduction of kidney filtration capacity.

PRINCIPLE

In alkaline medium, creatinine reacts with picrate (Jaffè reaction) forming a red-orange colored complex. The transformation speed of the colored complex, measured with a spectrophotometer during the first minutes of the reaction, is proportional to the creatinine concentration in the sample.

SAMPLE

Serum, non hemolyzed plasma.
Urine diluted 1:50 with distilled water.
Stability: 24 hours at 2-8°C

REAGENTS

Only for in Vitro diagnostics. Liquid reagents ready to use.

Package content	CL26-200S	CL26-400S
REAGENT 1 Sodium hydroxide 0,8 mol/L	2 x 50 ml	2 x 100 ml
REAGENT 2 Picric acid 15 mmol/L	2 x 50 ml	2 x 100 ml
STANDARD (Std) Creatinine 2 mg/dl (176,8 μmol/L)	1 x 4 ml	1 x 4 ml

Stability: reagents are ready to use. Store at 15-30°C and protect from light to keep the reagents stable up to the expiration date on the label. Keep bottles closed when not in use. Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

REAGENT PREPARATION

Mix 1 volume of Reagent 1 with 1 volume of Reagent 2.
Stability: 5 days at 20-25°C, 2 weeks at 2-8°C if stored in a closed bottle protected from light.

MANUAL ASSAY PROCEDURE

Method:	fixed time
Wavelength:	510 nm
Optical path:	1 cm
Temperature:	30 - 37°C
Reaction Time:	1 minute
Reading:	against air or distilled water
Sample/Reagent:	1/10

Bring the reagent to the chosen temperature for the analysis.

WARNING: as the reaction is particularly temperature sensible, make sure to work under constant thermal conditions.

Pipette in cuvette:

	Standard	Sample
Working reagent	1,0 ml	1,0 ml

Let it reach the chosen temperature and add:

Standard	0,1 ml	
Sample		0,1 ml

Stir and incubate for 30 seconds at the chosen temperature. Read the sample (AbsS1) and the standard (AbsStd1) absorbencies.
After exactly 1 minute from the first reading, read the sample (AbsS2) and the standard (AbsStd2) absorbencies.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the concentration in the sample using the following formula:

Serum / Plasma

[mg/dl] creatinine = (AbsS2 – AbsS1) / (AbsStd2 – AbsStd1) x 2

[μmol/l] creatinine = (AbsS2 – AbsS1) / (AbsStd2 – AbsStd1) x 176,8

Urine:

[gr/24h] creatinine = (AbsS2 – AbsS1) /(AbsStd2 – AbsStd1) x 1 x L/24h

[mmol/24h] creatinine = (AbsS2 – AbsS1)/(AbsStd2 – AbsStd1) x 8,85 x L/24h

REFERENCE VALUES

Serum:
male 0,6 ÷ 1,2 mg/dl (53 ÷106 μmol/L)
female 0,0 ÷ 1,0 mg/dl (44 ÷88 μmol/L)

Urine: 1 ÷1,5 g/24h (8,8 ÷ 13,3 mmol/L)

Clearance:
male 98 ÷ 160 ml/min.
female 95 ÷ 150 ml/min.

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multiparameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 0,07 mg/dl.

Linearity: up to 10 mg/dl (884 μmol/L).
For higher values, dilute the samples with saline solution and multiply the result by the dilution factor.

Precision:

Within run (n=10)	Average [mg/dl]	SD	CV %
Sample 1	1,69	0,04	2,55
Sample 2	4,08	0,09	2,19

Between run (n=20)	Average [mg/dl]	SD	CV %
Sample 1	1,71	0,05	2,70
Sample 2	4,11	0,09	2,25

Interferences:

Up to 1000 mg/dl of hemoglobin does not interfere. Up to 5 mg/dl of bilirubin does not interfere.

Correlation against a reference method: the correlation of FAR method (Y) against a reference method (X) gives this equation:

Y = 0,9294X + 0,16 r = 0,9998

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may cause severe eye irritation (H319). They also cause skin irritation (H315). In case of skin contact: rinse thoroughly with water. In case of contact with the eyes: rinse thoroughly for several minutes. If eye irritation continues, call a doctor.

REFERENCES

1. Bartels H., Bohmer M., Heierli C., Clin. Chim. Acta 37,193 (1972)
2. Larsen K., Clin. Chim. Acta 41,209 (1972).
3. Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. 1989

MANUFACTURER

FAR
Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY
tel +39 045 6700870
website http://www.fardiag.com
e-mail: order@fardiag.com
e-mail: fardiag@fardiag.com

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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