

Creatinine Jaffe Colorimetric – kinetic

IVD For in-vitro diagnostic and professional use only

λ_{max} 492 nm
Score at 2-8°C

INTENDED USE

For the quantitative determination of creatinine in human serum or heparinized plasma.

INTRODUCTION

Creatinine is the result of the degradation of the creatine, component of muscles, it can be transformed into ATP, that is a source of high energy for the cells. The creatinine production depends on the modification of the muscular mass, and it varies little and the levels usually are very stable. It is excreted by the kidneys. With progressive renal insufficiency there is retention in blood of urea, creatinine and uric acid. Elevated creatinine level may indicate renal insufficiency.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

The assay is based on the reaction of creatinine with sodium picrate as described by Jaffe.

Creatinine reacts with alkaline picrate forming a red complex. The time interval chosen for measurements avoids interferences from other serum constituents. The intensity of the color formed is proportional to the creatinine concentration in the sample.

REAGENTS

R 1		
Picric Reagent	Picric acid	27.5 mmol/L
R 2		
Alkaline Reagent	Sodium hydroxide	0.29 mol/L

If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

Precision

Mean(mg/dL)	Intra-assay (n=20)		Inter-assay (n=20)	
	CV	SD	CV	SD
0.5	2.78	0.07	3.97	0.20
1.0	2.78	0.07	3.97	0.20

Sensitivity

1 mg/dL, \pm 0.0407 Δ A /min.

Accuracy

Results obtained using ATLAS reagents (y) did not show systematic differences when compared with other commercial reagents (x). The results obtained using 30 samples were the following:
Correlation coefficient (r²) 0.99584.

Regression equation: y = 0.993x + 0.075

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Haemoglobin (3 g/L), Bilirubin (20 mg/dL), interferes. Glucose \pm 4 g/L do not interfere.

A list of drugs and other interfering substances with creatinine determination has been reported by Young.

NOTES

- Calibration with the aqueous Standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.
- Creatinine standard/proceed carefully with this product because due to its nature it can get contaminated easily.

REFERENCES

- Murray R.J. Creatinine. Kaplan A et al. Clin Chem. The C.V. Mosby Co. St Louis, Toronto, Princeton 1988. 1261-1266 and 838.

CREATININE STD	Creatinine aqueous primary standard 1 mg/dL
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EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 492 nm (490-500)
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PRECAUTIONS

- R1/Picric acid): Corrosive (C)R35-Causes severe burns.
- R2/NaOH): Irritant (Xi); R26/R33: Irritating to eyes and skin.S28: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.S37/39: Wear suitable gloves and eye/face protection.S45: In case of accident or if you feel unwell, seek medical advice immediately.

PREPARATION

- Working reagent (WR): Mix equal volumes of R2 Picric Reagent and R2 Alkaline reagent. The working reagent is stable for 15 days at (2-8°C) or 7 days at room temperature (15-25 °C).

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contamination presented during their use.
- Do not use reagents over the expiration date.
- Signs of reagent deterioration:
 - Presence of particles and turbidity.
 - Blank absorbance (A) at 492 nm \geq 0.05.

SAMPLES

- Serum or heparinized plasma
Creatinine stability: 24 hours at 2-8°C.
- Urine: Dilute sample 1/50 with distilled water. Mix. Multiply results by 50 (dilution factor).
Creatinine stability: 7 days at 2-8°C.

PROCEDURE

- Assay conditions:
Wavelength:492 nm (490-510)
- Blank
- Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AAC 2001.
- Burns A et al. Tietz Textbook of Clinical Chemistry, 5th ed AAC 1999.
- Tietz N W et al. Clinical Guide to Laboratory Tests, 5th ed AAC 1995.

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IPPCASAS2 Rev A (02.09.2023)

IVD	Catalogue number		Temperature limit
IVD	In-vitro diagnostic medical device		Cuvette
	Contains sufficient for one test and relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

Cuvette: 1 cm light path
Temperature:25°C / 15-25°C
2. Adjust the instrument to zero with distilled water.

3. Pipette into a cuvette:

	Blank	Standard	Sample
Vol (uL)	1.0	1.0	1.0
Standard (uL)	--	100	--
Sample (uL)	--	--	100

- Mix and start stopwatch.
- Read the absorbance (A1) after 90 seconds and after 90 seconds (A2) of the sample addition.
- Calculate: $\Delta A = A2 - A1$.

CALCULATIONS

$\frac{A_2 \text{ Sample} - A_2 \text{ Blank}}{\Delta A \text{ Standard} - \Delta A \text{ Blank}} \times 2 \text{ (Standard conc.)} = \text{mg/dL of Creatinine in sample}$

Conversion factor: mg/dL \times 0.4 = $\mu\text{mol/L}$

QUALITY CONTROL

- Control sera are recommended to monitor the performance of assay procedures.
- If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerance.

REFERENCE VALUES

	Male	Female
Serum /plasma	0.7 – 1.4 mg/dL \pm 0.3 – 123.7 $\mu\text{mol/L}$	0.6 – 1.3 mg/dL \pm 0.2 – 97.2 $\mu\text{mol/L}$
Urine 15-25mg/Kg/24h	10 – 20mg/Kg/24h	8 – 18 mg/Kg/24h

These values are for orientation purposes; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range:

From detection limit of 0.05 mg/dL to linearity limit of 30 mg/dL.

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