CREATININE

End Point Method-Jaffe Reaction (With deproteinisation)

IVD CE

PRODUCT CODE
CS007

INTENDED USE
This reagent is intended for in vitro quantitative determination of Creatinine in serum & plasma

CLINICAL SIGNIFICANCE
Creatinine is formed in muscles from Phospho Creatinine. It is an important form of energy, being a store of high-energy phosphate. Creatinine determinations have one advantage over Urea determination that it is not affected by a high protein diet.
Serum Creatinine is more specific & sensitive indicator of renal function. Simultaneous estimations of serum Urea & Creatinine provide better information. Serum Urea nitrogen, Creatinine ratio is > 15 in pre renal failure, & < 10 in renal failure.
Decreased levels are found in muscle dystrophy.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE
In the Jaffe reaction, Creatinine react with alkaline picrate to produce a reddish - orange color the intensity of which at 520 nm is directly proportional to the Creatinine concentration.

Alkali
Creatinine + sodium picrate ----------> Creatinine - picrate complex (reddish orange color)

REAGENT COMPOSITION

Creatinine R1	
Picric acid	35 mmol/L
Creatinine R2	
Sodium Hydroxide	320 mmol/L
Creatinine R3	
Creatinine Standard	2 mg/dL or 177 µmol/L
Creatinine R4	
TRICHLOROACETIC ACID	1.2 mol/L

REAGENT STORAGE AND STABILITY
The reagents are stable, if protected from light, up to the stated expiry date when stored at 15 - 25° C.

PREPARATION OF WORKING REAGENT
Mix 1 volume of Reagent 1(R1) with 1 volume of Reagent 2 (R2)
Ensure working reagent is at 15-30°C before use.

SPECIMEN
Serum is recommended, however heparinized plasma may also be used.
Creatinine is stable for 24 hours at 2-8° **C.**

PRECAUTION
To avoid contamination, use clean laboratory wares.
Avoid direct exposure of reagent to light.

DEPROTEINIZATION
To 1.0 mL of sample, add 1.0 mL of reagent 4 (TCA). Mix well and centrifuge at 5000 rpm X 10minutes. Take supernatant and use to test procedure below.

ASSAY

Wavelength	:	520 nm
Cuvette	:	1 cm light path
Temperature	:	20-30°C (see note 2)
Measurement	:	Against reagent blank

PROCEDURE

Pipette into cuvettes	Blank	Standard	Sample
Distilled Water	1000 µL	---	---
Standard	---	1000 µL	---
Sample	---	---	1000 µL
TCA	1000 µL	1000 µL	1000 µL
Mix well and centrifuge at 5000 rpm X 10 minutes			
supernatant	1000 µL	1000 µL	1000 µL
Working reagent	1000 µL	1000 µL	1000 µL
Mix well and wait exactly 20 minutes after adding working reagent, read absorbance against reagent blank.			

CALCULATION

$$\text{Serum Creatinine (mg/dL)} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times 2 \text{ (Std.conc.)}$$

To convert mg/dL to µmol/L multiply by 88.4

LINEARITY
This reagent is linear to 10 mg/dL
If the concentration is greater than linearity (10 mg/dL), dilute the sample 1+5 with physiological saline (NaCl; 9g/L) and repeat the assay. Multiply the result by 6.

NORMAL RANGE
Serum Creatinine

Male	0.7-1.4 mg/dL	62-124 µmol/L
Female	0.7-1.2 mg/dL	62-106 µmol/L

QUALITY CONTROL
All control sera with Creatinine value determined by this method may be used.

NOTES
1- The assay is not influenced by glucose 6g/l, bilirubin 20mg/l, ascorbic acid 10 mg/l, acetone 10mmol/L or acetoacetic acid 1 mmol/l.
2- Reagent is highly dependent upon temperature, so a constant reaction temperature is required for both standard and sample within one series.
3- Reagent 1 (picric acid) is a strong oxidizing agent avoid contact with skin. Wipe any spillages as picric acid is explosive.
4- Reagent 2 (NaOH) and reagent 4 TCA are caustic. Do not swallow, avoid contact with skin and mucous membrane.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBILOGRAPHY

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2- Young. D.S. et al.;Clin. Chem. 21,286D, 1975Trinder, P. Ann. Clin. Biochem, 6,24,1969.

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3- Tietz, N.W. (Ed,); Textbook of Clinical Chemistry, W.B. Saunders, 1271 , 1986

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