CREATININE (Kinetic) (R1-R2)

ENZOPAK

Jaffe (Modified)

Last update 09-2020

Ref. CC3-CRK.008, 120 ml

INTENDED USE

Reagent kit for quantitative estimation of Creatinine in serum or urine.

INTRODUCTION

Creatinine is an end product of creatine metabolism which is a part of energy utilization mechanism in muscles. The quantity of creatinine generated depends marginally on the dietary protein intake. The serum creatinine level depends directly on the body muscle mass and is affected by intense muscular stress.

In 1886, Jaffe developed a method for the assay of creatinine based upon the reaction between creatinine and sodium picrate. In 1904, Folin employed this reaction for the quantitative estimation of creatinine, in urine. Since then, a number of modifications have been formulated to reduce interference from proteins and non-creatinine substances like keto-acids, glucose, ascorbic acid etc.

Creatinine is a modified formulation of Jaffe's reaction which does not require deproteinization. The picrate and alkali reagents are formulated in such a way that while measuring the rate of reaction, interference from non-creatinine substances present in the sample is almost eliminated.

DIAGNOSTIC SIGNIFICANCE

Creatinine is a waste product formed in muscle from the high energy storage compound, creatine phosphate. The amount of creatinine produced is fairly constant and is primarily a function of muscle mass. Creatinine is removed from plasma by glomerular filtration and then excreted in urine without any appreciable resorption by the tubules.

Creatinine is used to assess renal function, however, serum creatinine levels do not start to rise until renal function has decreased by at least 50%. Congestive heart failure, shocks and mechanical obstruction of urinary tract may also contribute to an elevated level of serum creatinine. An elevated serum creatinine level due to obstruction may rapidly fall when the obstruction is removed by surgery.

Many times serum urea/creatinine ratio is used for assessment of kidney function and differential diagnosis. Creatinine clearance test is carried out for assessment of kidney function only.

PRINCIPLE

Creatinine present in the serum or urine reacts with alkaline picrate to form a colored complex. The rate of formation of colored complex is directly proportional to creatinine concentration. This rate of reaction (intensity of color produced) is measured photometrically at 510 nm and is compared with that of the standard.

Creatinine + Alkaline Picrate $\longrightarrow$ Creatinine Picrate Complex

PRESENTATION

All the reagents to be stored at 2-8^{0}C	No. of Bottles 120 ml
• 1 Creatinine (Picrate Reagent)	1
• 2 Creatinine (Alkali Reagent)	1
• Creatinine Standard (2 mg/dl)	1

FINAL REAGENT COMPOSITION

Active Ingredients	Concentration
• Picric Acid	20 mmol/L
• Sodium Hydroxide	100 mmol/L
• Standard (2 mg/dl)	

Also contains non-reactive fillers and stabilizers.

PRECAUTION

Creatinine is for *IN-VITRO* diagnostic use only. Avoid contact of the reagents with skin, eyes and clothes. Use of automated pipetting devices.

Reagent contains Sodium azide. DO NOT INGEST.

PREPARATION OF WORKING REAGENT

Prepare working reagent by combining one volume of 1 Creatinine with one volume of 2 Creatinine. Mix well before use.

REAGENT STORAGE AND STABILITY

All the reagents included in the kit are stable at 2-8^{0}C until the expiry date printed on the label.

The working reagent is stable at 2-8^{0}C for 90 days.

SPECIMEN COLLECTION

Fresh, clear serum with no hemolysis is the specimen of choice. Plasma prepared using heparin as an anticoagulant may also be used.

REACTION PARAMETERS

• Type of Reaction	: Fixed Time/Two Point
• Wavelength	: 510 nm
• Flowcell/Cuvette Temperature	: 30^{0}C
• Delay Time	: 20 seconds
• Interval	: 60 seconds
• Measuring Time	: 80 seconds
• No. of readings	: 2
• Standard/Sample Volume	: 100 microliters (0.1 ml)
• Standard Concentration	: 2 mg/dl
• Working Reagent Volume	: 1.0 ml
• Light Path	: 1.0 cm
• Zero setting with	: Distilled Water

TEST PROCEDURE

Pipette Into Test Tubes	STANDARD	TEST
Working Reagent (ml)	1.0	1.0
Standard (ml)	0.1	-
Sample (ml)	-	0.1

Mix and aspirate. Record the absorbance of Standard (ST) and Test (TS) at 20 seconds (ST_1, TS_1) and again at 80 seconds (ST_2, TS_2) at 510 nm, against distilled water.

TEST RESULT

$$\text{Creatinine (mg/dl)} = \frac{(TS_2 - TS_1)}{(ST_2 - ST_1)} \times 2$$

To convert (mg/dl) to micromol/liter, use the following equation, micromol/liter = (mg/dl) x 88.5

LIMITATIONS FOR INTERFERENCE

As per studies carried out for interference, following results were obtained.

- No Interference from Hemoglobin upto 50 mg/dl.
- No Interference from free Bilirubin upto 12 mg/dl.
- No Interference from Lipemic (Measured as Triglycerides) upto 500 mg/dl.

NORMAL VALUES

(For Serum)

Men: 0.9-1.4 mg/dl
Women: 0.6-1.2 mg/dl

CREATININE ESTIMATION IN URINE

For Creatinine estimation in urine, dilute the sample suitably with distilled water and follow the procedure to calculate test results by applying dilution factor. Dilution of 1:15 to 1:100 is suggested.

Creatinine concentration in urine (gms/lit)

$$= \frac{(TS_2\text{-}TS_1)}{(ST_2\text{-}ST_1)} \times 2 \times \frac{\text{dilution factor}}{100}$$

NORMAL VALUES

(For Urine)

Men: 1.0–2.0 gms/24 hrs.
Women: 0.8–1.5 gms/24 hrs.

LINEARITY

This method is linear upto 12 mg/dl. For sample values higher than linearity limit, dilute the samples suitably with 0.9 % saline and repeat the assay. Apply dilution factor to obtain test results.

REFERENCES

1. KAPLAN A., SZABO, L.L., Clinical Chemistry: Interpretation and Techniques, Lea and Febiger, Philadelphia (1983).

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91·265·2281631
Email: mail@reckondiagnostics.com
An ISO 13485:2016 Certified Company