

SAFETY PRECAUTIONS AND WARNINGS :

This reagent is for *In vitro* diagnostic use only.

INTENDED USE :

This reagent kit is intended for "*in vitro*" quantitative determination of Creatinine concentration in serum & urine. A colorimetric, alkaline picrate method (Jaffé).

CLINICAL SIGNIFICANCE :

Creatinine is released during metabolism of creatine phosphate, and is excreted by the kidneys. Creatinine concentration in blood and in urine represents a primary indicator for renal function, especially that for glomerular filtration. Increased levels are associated with acute renal impairment, chronic nephritis, obstruction of the urinary tract, strong physical overloading. Low creatinine concentrations are found in conditions with juvenile diabetes mellitus, pregnancy and muscular dystrophy.

PRINCIPLE :

Creatinine forms with alkaline picrate (in ratio of 1:1) a colored creatinine picrate complex containing ionic bonds. The rate of formation of the colored complex is proportional to the creatinine concentration.

REAGENT COMPOSITION :

Reagent 1 : Alkaline Reagent
Reagent 2 : Picrate Reagent
Creatinine standard: 2.0 mg/dl

MATERIALS REQUIRED BUT NOT PROVIDED :

- Clean & Dry Glassware.
- Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

SAMPLES :

Serum free of haemolysis.
12 h or 24 h collected urine. Urine must be diluted in ratio of 1:100 with distilled water.

STABILITY OF REAGENT :

When Stored tightly closed at room temperature, protected from light and contaminations prevented during their use; reagents are stable up to the expiry date stated on the label.

WORKING REAGENT :

Mix Reagent 1 with Reagent 2 in a ratio of 1:1.

GENERAL SYSTEM PARAMETERS :

Reaction type	Fixed Time
Wave length	492 nm (480 - 520 nm)
Light Path	1 Cm
Reaction Temperature	37°C
Blank / Zero Setting	Distilled Water
Reagent Volume	1ml
Sample Volume	100 µl
Delay / Lag Time	30 Seconds
Read Time	60 Seconds
Read Interval	60 Seconds
Standard Concentration	2.0 mg/dl
Low Normal	0.7 mg/dl
High Normal	1.3 mg/dl
Linearity	25 mg/dl

ASSAY PROCEDURE :

	Standard	Sample
Reagent	1ml	1ml
Standard	100 µl	
Sample		100 µl

Mix well and after 30 secs incubation read initial absorbance A1. Exactly after 60 seconds interval read absorbance A2.

Determine the Δ Absorbance.

$$\Delta \text{Abs.} = A2 - A1$$

CALCULATION :

$$\text{Creatinine Conc. (mg/dl)} = \frac{\Delta \text{Abs. of Sample}}{\Delta \text{Abs. of Standard}} \times \text{Conc. of Standard}$$

LINEARITY :

Reagent is Linear up to 25 mg/dl.

Dilute the sample appropriately and re-assay if Creatinine concentration exceeds 25 mg/dl. Multiply result with dilution factor.

REFERENCE NORMAL VALUE :

Serum: Male : 0.7-1.3 mg/dl (62-115 mol/l)
Female: 0.5-1.2 mg/dl (44-106 mol/l)
Urine : 7-16 mmol/l/24h

QUALITY CONTROL :

For accuracy it is necessary to run known controls with every assay.

LIMITATION & PRECAUTIONS :

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assay bring all the reagents to room temperature.
4. Avoid contamination of the reagent during assay process.

BIBLIOGRAPHY :

Henry, J.B, Young D.S, teitz N.W, Vasilades, J, Can, Chem(1972), 18.

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