CREATININE TEST KIT

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

PRINCIPLE : Creatinine forms with alkaline picrate (in ratio of 1:1) a colored Creatinine picrate complex containing ionic bounds. 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 hemolysis. 12 h 24 h collected urine. Urine must be dilluted in ratio of 1:100 with distilled water.

STABILITY OF REAGENT : When Stored tightly closed at room temperature, protected from light and contaminations prevanted during their use; reagents are stable up to the expiry date stated on the lable.

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

ASSAY PROCEDURE :

	Standard	Sample
Reagent	**1000 µl**	**1000 µl**
Standard	**100 µl**	**-**
Sample	**-**	**100 µl**

Mix well and after 30 seconds incubation read initial absorbance A1. Exactly after 90 seconds interval read absorbance A2.
Determine the Δ Absorbance.
Δ Abs. = A2 - A1

GENERAL SYSTEM PARAMETERS :

Reaction Type	**Fixed Time**
Wavelength	**505 nm (480 - 520) nm**
Light Path	**1cm**
Reaction Temperature	**37°C**
Blank / Zero Setting	**Distilled Water**
Reagent Volume	**1000 µl**
Sample Volume	**100 µl**
Delay / Lag Time	**30 Seconds**
Read Time	**60 Seconds**
Read Interval	**90 Seconds**
Standard Concentration	**2.0 mg/dl**
Low Normal	**0.7 mg/dl**
High Normal	**1.3 mg/dl**
Linearity	**20 mg/dl**

CALCULATION :

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

LINEARITY : Reagent is Linear up to 20 mg/dl. Dilute the sample appropriately and re-assay if Creatinine concentration exceeds 20 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.

SENSITIVITY / LIMIT DETECTION : The Lower Limit of detection is 0.2 mg/dl (17.7 µmol /L).

LIMITATION & PRECAUTIONS :

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

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

Mfd. In India By:
PRECILAB REAGENTS & CHEMICALS PVT. LTD.
A / F-6 & F-8, Udyog Bhawan - 2, Plot K - 3, MIDC,
Ambernath (E), Thane, Maharashtra - 421506, INDIA.

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