

Reagent kit for quantitative estimation of Creatinine in Serum, Plasma & Urine.

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.

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.



SPECIMEN COLLECTION:

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

Urine of 24 hrs. collection is preferred. (Dilute urine 1:50 in distilled water). i.e. 1 ml Urine + 49 ml Distilled Water

KIT PRESENTATION:

Pack	R1-Creatinine (Buffer)	R2-Creatinine (Picric Acid)	Creatinine Standard
2 X 50 ml	1 X 50 ml	1 X 50 ml	1 X 02 ml
4 X 50 ml	2 X 50 ml	2 X 50 ml	1 X 02 ml
4 X 100 ml	2 X 100 ml	2 X 100 ml	1 X 03 ml
10 X 100 ml	5 X 100 ml	5 X 100 ml	1 X 05 ml

WORKING REAGENT PREPARATION:

Preparation Working Reagent by Mixing equal volumes of **R1-Creatinine (Buffer) with R2-Creatinine (Picric Acid)**. The Working Reagent is stable for 30 days at RT.

REAGENT STORAGE & STABILITY:

All reagents included in the kit are stable at RT until the expiry date stated on the label.

LINEARITY:

The method is **linear up to 20 mg/dl**. If the values exceed this limit, dilute the sample with Distilled Water and repeat the test. Multiply the result with dilution factor.

ASSAY PARAMETERS:

Reaction	: Fix Time	Sample Volume	: 100 µl
Wavelength	: 505 nm	R1 + R2 Volume	: 500 µl + 500 µl
Flow Cell Temp.	: 37°C	Std Conc.	: 2 mg/dl
Initial Delay	: 30 Sec	Reaction Slope	: Increasing
Interval Time	: 60 Sec	Zero Setting	: Distilled Water
Read Time	: 60 Sec	Linearity	: 20 mg/dl
No. of Reading	: 01	Unit	: mg/dl

PROCEDURE:

Pipette into TT	Standard	Test
R1-Creatinine (Buffer Reagent)	500 µl	500 µl
R2-Creatinine (Picric Acid Reagent)	500 µl	500 µl
Creatinine Std (2mg/dl)	100 µl	--
Sample (Test)	--	100 µl

Mix & aspirate immediately and read difference in absorbance between 30 seconds (AT₁) and 90 seconds (AT₂) for Standard and Test at 505 nm.

CALCULATION:

$$\text{Serum/Plasma Creatinine (mg/dl)} = \frac{\Delta \text{Abs of Test} \times 2}{\Delta \text{Abs of Standard}}$$

$$\text{Urine Creatinine (gm/L)} = \frac{\Delta \text{Abs of Test} \times 2 \times \text{Dilution Factor}}{\Delta \text{Abs of Standard} \times 100}$$

Where $\Delta \text{Abs} = (\text{AT}_1) - (\text{AT}_2)$

$$\text{Urine Creatinine (gm/24 hrs)} = \text{Urine Creatinine in gm/L} \times \text{Vol. of Urine 24 hrs (in Liter)}$$

NORMAL VALUES:

Serum/Plasma Creatinine

Male: 0.6 – 1.4 mg/dl **Female:** 0.5 – 1.2 mg/dl

Urine Creatinine (gm / 24 hrs)

Male: 1.0 – 2.0 gm/ 24 hrs **Female:** 0.8 – 1.8 gm/24 hrs

Each laboratory should establish its own reference range.

REFERENCE:

1. KAPLAN A., SZABO, L.L., Clinical Chemistry: Interpretation and Techniques, Lea and Febiger, Philadelphia (1983).
2. BOWERS, L.D. (1980) Clin. Chem. 26:551.

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Expiry Date



In-Vitro Diagnostics Use



Storage



Mfg. Date



Batch Number



Catalogue Number



See Package Insert