

Intended Use:

Kit for the for the quantitative determination of Creatinine in human serum, plasma and Urine

Summary and Clinical Significance

Creatinine is a waste product excreted by the kidneys mainly by glomerular filtration. The concentration of creatinine in plasma of a healthy individual is fairly constant, independent from water intake, exercise and rate of urine production. Therefore increased plasma creatinine values always indicate decreased excretion, i.e. impaired kidney function. The creatinine clearance enables a quite good estimation of the glomerular filtration rate (GFR) which allows better detection of kidney diseases and monitoring of renal function.

Principle: Fixed Time

Picric acid in an alkaline medium reacts with Creatinine to form an Orange Colored Complex with the Alkaline Picrate. Intensity of the colour formed during the fixed time is directly proportional to the amount of Creatinine present in the Sample.

Reference Values:

	Serum	Urine
Males :	0.6 - 1.3 mg/dl	1.0 - 2.0 gm/24 hrs.
Females :	0.6 - 1.2 mg/dl	0.8 - 1.8 gm/24 hrs.

It is recommended that each laboratory should establish its own normal range representing its patient population.

Reagent Composition:

Picric acid	- > 8.0 mMol/L
Sodium hydroxide	- > 175 mMol/L
Boric Acid	- > 2 mMol/L mMol/L
EDTA	- > 1.8 mMol/L
Activators and stabilizers	

Storage and Stability:

All the reagents are stable at Room Temperature till the expiry date mentioned on the labels.

Specimen:

- 1) Unhemolysed Serum is the preferred Specimen.
- 2) In case of Creatinine Clearance Test, 24 hours Urine is preferred. Dilute Urine 1:100 with distilled water before assay and multiply the results with the dilution factor.

Reagent Preparation:

Reagent-1 and Reagent-2 are ready to use and there is no need to make a working reagent. Sequence of reagent addition should be followed as per the pack insert

System Parameters: Fixed Time

Reaction Type	: Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	: Increasing
Sample Volume	: 50 µl
Reagent Volume	: 500 µl R1 + 500 µl R2
Wave Length	: 505 nm (500-520 nm)
Standard Conc.	: 2.0
Flow Cell Temp.	: 37°C
Linearity	: 25.0
Zero setting with	: Distilled Water
Units	: mg/dl
Delay	: 30 sec.
Measuring	: 90 sec
Low Normal	: 0.6
High Normal	: 1.3 (Males)

Notes:

- 1) If the Creatinine value exceeds 25 mg/dl dilute the specimen with equal volume of distilled water and re assay. Multiply the results by 2 to obtain correct Creatinine value.
- 2) It is recommended to run the Creatinine standard with each and every assay batch.
- 3) The Creatinine Determination may be affected by the presence of large quantities of reducing substances.

Procedure Fixed Time:

	(S)	(T)
Reagent -1	500 µl	500 µl
Standard (Conc. : 2.0 mg/dl)	50 µl	----
Sample	----	50 µl
Reagent -2	500 µl	500 µl

Mix well and immediately aspirate in to the Analyzer. Read absorbance of Standard (S) and Test (T) against distilled water at 505 nm (500- 520 nm) as follows:

Initial absorbance A₀ -exactly after 30 sec (Delay)
Final absorbance A₁ -exactly 90 sec.(Measuring)

Determine Δ A for Standard (S) and Test (T)

Calculations:

$$\text{Serum Creatinine (mg/dl)} = \frac{\Delta AT}{\Delta AS} \times 2 \text{ (Standard Concentration)}$$

$$\text{Urine Creatinine (gm/L)} = \frac{\Delta AT}{\Delta AS} \times 2 \times 100 \text{ (Urine Dilution Factor)}$$

(For urine Creatinine user should convert results obtained in mg/dl into gm/L)

Urine Creatinine / 24 hours = Urine Creatinine in gm/L. x 24 hours urine volume collected in litres.

References:

- 1) Browsers L.D. (1980) Clin. Chem 26 : 551
- 2) Browsers L.D. et al. (1980) Clin. Chem. 26 : 655.
- 3) Text book of Clinical Chemistry 3rd edition,
Edited by N.W. Tietz P1271 - 1280. W.B.Saunders
Co.Philadelphia. PA,1986.

Ordering Information:

Ref./Cat. No.	Pack Size
P-CRE(F) 100	2 x 50 ml
P-CRE(F) 200	4 x 50 ml
















Product Features

- Liquid Stable, Ready to use Two Reagents
- Fixed Time Procedure
- 2 minutes fixed time reaction
(30 Sec Delay +90 Sec Measuring).
- Aqueous Creatinine standard provided
- Lipid Clearing Factor (LCF)
- Linearity: 25 mg/dl
- Measuring Wavelength 505 nm (500 – 520 nm)
- Serum / Heparinized or EDTA Plasma/ Diluted Urine
as Specimens
- Available as multipurpose reagents and dedicated
system packs



**Pariksha
Biotech**
A game changer in IVD

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limit		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		



Manufactured in India by :
Pariksha Biotech Pvt Ltd,
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