Lifechem™ - CREATININE-LR

(MODIFIED JAFFE'S METHOD)

CLINICAL SIGNIFICANCE:

Creatinine is an endogenous non-protein nitrogen waste product formed from the high energy storage compound. Creatinine is removed from the plasma by glomerular filtration and then excreted in urine.

Elevated serum Creatinine levels are usually indicative of renal impairment. Unlike Urea, Creatinine levels are unaffected by protein catabolism or other external factors, and hence a better indicator of renal function. So, for the diagnosis of renal disease, serum Creatinine is preferred over urea estimation. In addition to renal diseases, elevated levels may be observed in urine and serum during extensive muscular dystrophy.

TEST PRINCIPLE:

Picric acid in an alkaline medium reacts with Creatinine to form an orange coloured 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.

Creatinine + Picric acid $\xrightarrow{\text{Alkaline Medium}}$ Orange Coloured Complex

NORMAL RANGE:

Serum		Urine
Male	0.6-1.5 mg/dl	1.1-2.0 gm/24 hrs.
Female	0.5-1.2 mg/dl	1.0-1.8 gm/24 hrs.

KIT CONTENTS:	**Code No.**
	KCL1
	(2X50 ml)
Reagent 1. Liquichem Creatinine reagent	2 x 50 ml
Reagent 2. Creatinine Standard (2.0 mg/dl)	5ml

SPECIMEN:

Unhemolysed serum / urine.
In case of Creatinine Clearance Test, 24 hrs urine is preferred. Dilute urine 1:100 with distilled water before use.

WORKING REAGENT PREPARATION:

The reagent is ready-to-use and is stable at 2-8^{0}C till the expiry date mentioned on the labels.

PROCEDURE:

Pipette into test tubes labelled standard (S) and Test (T) as follows:

	(S)	(T)
Creatinine reagent	1.0 ml	1.0 ml
Standard (2.0 mg /dl)	100 µl	—
Specimen	—	100 µl

Reaction temperature: 37^{0}C

Mix well and read absorbance of S and T against distilled water at 520 nm (500 –520 nm) as follows:

Initial absorbance A_0 – Exactly after 30 Sec.
Final absorbance A_1 – Exactly after 90 sec. after A_0

Determine ΔA for Standard (S) and Test (T)

$\Delta AS = AS_1 - AS_0$
$\Delta AT = AT_1 - AT_0$

CALCULATIONS:

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

$$\text{Urine Creatinine (g/L)} = \frac{\Delta AT}{\Delta AS} \times 2$$

Urine Creatinine / 24 hours = Urine Creatinine in g/L x Vol. of Urine in 24 hours collected in Litres.

QUALITY CONTROL:

It is recommended to include Assayed Quality Control Serum (Level I & II) with each assay batch to verify the performance of the procedure. Failure to obtain the proper range of values in the assay of control sera may indicate either reagent deterioration, instrument malfunction or procedural errors.

SYSTEM PARAMETERS:

Reaction type	: Fixed Time/ Initial Rate/ Two point kinetic		
Wave length	: 520 nm (505-570)	Standard Conc.	: 2
Flow Cell Temp.	: 37^{0}C	Units	: mg/dl
Reagent volume	: 1000µl	Sample volume	: 100µl
Delay Time	: 30 Sec	Fixed Time	: 90 Sec
Blank	: D.Water	Slope of Reaction	: Increasing
Low normal	: 0.6	High normal	: 1.5

NOTES:

1. Adherence to the reaction time should be meticulously followed.
2. The normal range is approximate and varies with the sex and body weight.
3. It is always recommended to run quality control sera in every 30 days to check the reagent performance
4. Control results falling outside the upper or lower limits of the established ranges indicate that the assay may be out of control. The following corrective measures are recommended in such situations.
   (a) Run the same control again
   (b) If repeatedly the control results are outside the established range, prepare fresh control serum and repeat the test.
   (c) If the results are still out of the established range, recalibrate the reagent with fresh Standard/Calibrator, then repeat the test.
   (d) If the results are still out of the established range, perform a calibration with fresh reagent and repeat the test.

LINEARITY:

The kit is linear up to 20 mg/dl.

BIBLIOGRAPHY:

1. Browers, L.D.,(1980), Clin.Chem ,26:551
2. Text book of Clinical Chemistry,3rd edition, Edited by N.W.Tietz P 1271 1280 W.B.Saunders Co., Philadelphia. PA. 1986.
3. Bartels, H. *et al,*(1971),Clin.Chem.Acta,32 : 81.

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