CREATININE

(Modified Jaffe's Method)

Liquid Reagent

INTENDED USE:

This reagent kit is used for *in-vitro* quantitative determination of Creatinine in human serum, plasma and Urine.

SUMMARY:

Creatinine is excreted as a waste product by the kidneys. Increased serum creatinine levels usually indicate impairment of renal function. Creatinine appears in the glomeruler filtrate and it is not reabsorbed by the tubule. Hence any condition that reduces the glomeruler filtration rate will result in the increase of creatinine concentration in plasma.

Creatinine is the catabolic product of Creatinine Phosphate, which is used by the Skeletal Muscle. The daily production of Creatinine depends on muscular mass and it is excreted out of the body entirely by the kidneys. Elevated levels are found in Renal Dysfunction Reduced Renal Blood Flow (Shock, Dehydration, and Congestive Heart Failure) and Diabetes Acromegaly. Decreased levels are found in Muscular Dystrophy.

PRINCIPLE:

Picric acid in an alkaline medium reacts with creatinine to form an orange coloured complex with alkaline picrate. Intensity of the colour formed during the fixed time is directly proportional to the amount of creatinine present in the sample.

KIT CONTENTS:

Reagent 1 : Creatinine Reagent

Reagent 2 : Creatinine Standard (2 mg/dl)

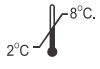
Product Insert : 01 No.

WORKING REAGENT:

The reagents of Creatinine Liquid Reagent are ready to use

NOTE: Cap the reagent bottle tightly when the reagent is not in use.

STORAGE AND STABILITY:



All the reagents must be stored at 2-8°C and are stable till expiry date mentioned on the labels.

SPECIMEN COLLECTION & STORAGE :

- Serum or Heparinised Plasma.
- Creatinine determination in urine is usually carried out on a 24 hour urine sample. Thymol or toluene should be used as preservatives. The 24 hours urine sample should be thoroughly mixed and diluted to 1:50 with distilled water. The diluted urine sample is used to carry out creatinine estimation.
- No deproteinization of sample is required. Samples should be used on the same day. If necessary, they may be preserved at 2-8°C for 48 hours. Samples should be brought to room temperature prior to use.

PRECAUTIONS :

1. For *in-vitro* diagnostics use only.
2. Do not inhale the reagent or pipette by mouth.
3. Avoid contact with skin/eyes, In case of contact wash off immediately with plenty of water and seek medical attention as early as possible.
4. Before the assy bring all the reagents to room temperature.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.

NOTE: Cap the reagent bottle tightly when the reagent is not in use.

PROCEDURE (Automated):

Refer to specific instruments application instructions.

TEST PROCEDURE (Manual):

Wavelength : 510 nm & Reaction Temperature : 37°C.

Pipette into Test Tube	Standard	Test
Creatinine Reagent	1.0 ml	1 ml
Standard	100 µl	-
Sample	-	100 µl
Mix and record the change in absorbance of test (ΔA_T) and standard (ΔA_s) between 30 seconds and 120 seconds.		

CALCULATIONS:

$$\text{Serum Creatinine concentration (mg/dl)} = \frac{\Delta A_T}{\Delta A_s} \times 2 \text{ (Concentration of Standard)}$$

To convert mg/dl to µmol/l

$$\mu\text{mol/l} = \text{mg/dl} \times 88.5$$

$$\text{Urine Creatinine concentration (mg/dl)} \frac{\Delta A_T}{\Delta A_s} \times 2 \times 50^*$$

* Dilution factor

NORMAL VALUES* :

	Men	Women
Urine Creatinine	1.5 - 2.0 gm/24 hrs.	0.8 - 1.5 gm/24 hrs.
Serum Creatinine	0.4 - 1.5 mg/dl	0.4 - 1.5 mg/dl

* It is recommended that each labrotary should establish its own normal range.

CLINICAL SIGNIFICANCE:

Elevated levels of serum or plasma creatinine are associated with renal failure or muscular dystrophy. Serum creatinine levels start rising only when the renal function has declined by atleast 50%. Increased levels of creatinine are also indicative of congestive heart failure, shock and mechanical obstruction of

the urinary tract. Enhanced levels of serum creatinine due to obstruction rapidly fall when the obstruction is removed surgically.

PERFORMANCE CHARACTERISTICS:

1. **LINEARITY:** 25 mg/dl.

2. COMPARISION:

Validation studies establish that Creatinine Liquid Reagent has excellent accuracy and reproducibility.

For accuracy comparative studies were conducted on random samples using Creatinine Liquid Reagent and a reference method. The resultant coefficient of correlation was 0.99 and the corresponding regression equation was y=1.10234 x -0.3365.

3. PRECISION:

For precision within run and run to run studies were carried out using controls having normal and abnormal values (0.87 - 5.3mg/dl). The detail is as below.

Within Run			Run to Run		
Mean	**S.D.**	**C.V.%**	**Mean**	**S.D.**	**C.V.%**
1.20	0.05	1.8	1.20	0.005	3.0
3.68	0.07	1.2	3.89	0.9	1.4
1.22	0.04	0.9	1.17	0.06	2.0
4.38	1.0	1.2	1.2	1.2	1.5

4. SPECIFICITY

The method is specific for creatinine. It is relatively free of interference from commonly occuring substances in serum or plasma.

AUTOMATED APPLICATIONS:

Creatinine Liquid Reagent can be used with Hitachi 700 series, RA 1000, 2000, XT, Express 550 plus, Syncron CX4, Lisa 200, BTR 810/820/830, RA 50, Erbachem-5 plus.Ranlab 125, Ranlab 40 etc.

Application sheets for use on specific semi automatic, batch and auto analysers are available on request.

Input parameters for semi auto / auto analysers are given below

INPUT PARAMETERS	VALUES
Type of reaction	Initial Rate, Kinetic
Slope of reaction	Increasing
Wavelength	510 nm
Standard concentration	2 mg/dl
Incubation time	30 sec.
Interval time	90 sec.
Interval No.	1
Flowcell temperature	37°C
Units	mg/dl
Upper Normal value (serum)	1.5 mg/dl
Lower Normal value (serum)	0.4 mg/dl
Linearity	25 mg/dl
Creatinine Reagent volume	1 ml
Sample / Standard volume	100 µl

QUALITY CONTROL:

For accuracy, it is necessary to run known serum controls with each assay.

REFERENCES:

1. Jaffe M.1886. 2 tschr physiol whem. 10:391.
2. Wolf P.L. et.al.1972. Methods and techniques in Clin Chem. Wiley-Interscience, New York.
3. Henry, J. B., ed., Clinical Diagnostics and Management by Laboratory Methods, 18th Edition, W.B. Saunders, Philadelphia.

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