Pariksha Biotech
A game changer in IVD

Creatinine Estimation Kit

High-Q Creatinine- ML

Modified Jaffe's Method

HIGH®
Command on Quality

Intended Use:
Kit for the quantitative determination of Creatinine in Human Serum, Plasma and Urine by Fixed Time Method

Clinical Significance :
Creatinine assays are most frequently performed to aid in the determination of renal function.

Method History :
In 1886, Jaffe described a method for the determination of creatinine involving a protein free filtrate and a reaction with picric acid in alkaline solution. Although several methods have been described since then, the classic Jaffe reaction is still the most widely used. The Jaffe reaction is subject to interferences by a number of substances, including protein and glucose. Modifications of the procedure have been developed to combat the drawbacks. The kinetic procedures have become popular because they are fast, simple and avoid interference. The present method is based on a modification of the above procedure, incorporating a surfactant and other ingredients to minimize protein and carbohydrate interferences.

Principle

Alkali
Creatinine + Sodium Picrate ----------> Creatinine-picrate complex (yellow-orange)

Creatinine reacts with picric acid in alkaline conditions to form a color complex that absorbs at 510 nm. The rate of formation of color is proportional to the creatinine 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	-	≥ 250 mmol/L
Surfactant		

Storage and Stability
High-Q Creatinine-ML is available as ready to use single liquid reagent and it does not need any reconstitution. All the reagents are stable till the expiry date mentioned on the labels when properly stored at 2-8^{0}C and the contamination is avoided

Specimen
1) Serum / Plasma is the preferred Specimen.
2) Urine (dilute 1:100 with distilled water before assay).

Procedure:
Pipette into test tubes labeled Standard (S) and Test (T).

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

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

Initial absorbance A_0 - Exactly after 30 sec.
Final absorbance A_1 - Exactly 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 :

$$\text{Serum Creatinine (mg/dl)} = \frac{\Delta AT}{\Delta AS} \times 2.0 \text{ (Standard Concentration)}$$

$$\text{Urine Creatinine (gm/L)} = \frac{\Delta AT}{\Delta AS} \times 2.0 \times 100 \text{ (Urine Dilution Factor)}$$

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

Urine Creatinine / 24 hours = Urine Creatinine in gm/L. × Vol. of Urine in 24 hours collected in Litres.

Very Important Suggestions:

It is always advisable to run Creatinine Standard provided in the kit or any Serum based Calibrator with each and every test batch and derive the Factor to get satisfactory results. (A limitation in Two Point / Fixed Time Chemistries.)

[OR]

Calibrate the Reagent with the Creatinine Standard or Calibrator every 24 hours.

It is always recommended to run commercially available Quality Control Sera in every 30 days to check the Reagent as well as Instrument performance

It is essential to maintain the indicated reaction timings and temperature meticulously during the test procedure.(User should always connect the analyzer to Constant Power Supply)

- To ensure good Quality Control Normal and Abnormal Commercial Quality Control Sera should be run as Samples to check the reagent as well as instrument performance.
- It is always advisable to run Quality Control Sera in every 30 days to check the reagent performance.
- 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.

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System Parameters:

Reaction Type : Fixed Time / Initial Rate / Two Point Kinetic

Reaction Direction	:	Increasing
Sample Volume	:	100 µl
Reagent Volume	:	1000 µl
Wave Length	:	505 nm (500-520 nm)
Standard Conc.	:	2.0
Flow Cell Temp.	:	37^{0}C
Linearity	:	25.0
Zero setting with	:	Distilled Water
Units	:	mg/dl
Delay	:	30 sec.
Interval	:	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 reassay. Multiply the results with 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.
4) It is essential to maintain the indicated reaction timings and Temperature meticulously during the test procedure.

References:

1) Browers. L.D. (1980) Clin. Chem 26 : 551
2) Browers 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.
4) Fabiny, D.L., Ertingshausen, G., Clin. Chem. 17:391 (1971).
5) NCCLS document "Protection of Laboratory Workers form Infectious Disease Transmitted by Blood, Body Fluids, and Tissue", 2nd Ed. (1991).
6) Young, D.S. et al, Clin. Chem. 21:1D (1975).
7) NCCLS document "Interference testing in Clinical Chemistry", 2nd Ed. (1992).
8) NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed., (1992).

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Ordering information:

Ref./Cat.	Pack Size	Presentation
P-CRE (ML) -100	4 x 25 ml	**Mono Reagent**
P-CRE (ML) - 250	5 x 50 ml	
P-CRE (ML) - 500	10 x 50 ml	

Product Features

- Liquid Stable, ready to use mono reagent
- 2 minutes fixed time reaction (30 sec Delay +90 sec Interval).
- Aqueous creatinine standard provided (Standard Conc: 2 mg/dl)
- 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

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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Manufactured in India by :
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