CREATININE

METHOD – JAFFE (ALKALINE PICRATE)
PRODUCT CODE – LC07

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Creatinine in serum / plasma using Jaffé method.

SUMMARY AND PRINCIPLE

Creatinine concentration in blood and in urine represents a primary indicator for renal function, especially that for glomerular filtration. Increased levels are associated with acute renal impairment, chronic nephritis, obstruction of the urinary tract, strong physical overloading. Low Creatinine concentrations are found in conditions with juvenile diabetes mellitus, pregnancy, and muscular dystrophy. Creatinine is a reagent set for determination of Creatinine in human serum & plasma based on initial rate method using alkaline picrate. Creatinine reagent is a single reagent system with one step reconstitution. It involves mixing of picrate and diluent reagent.

Creatinine + Picrate $\xrightarrow{\text{Alkaline Medium}}$ Orange Colour

KIT COMPONENTS

Reagent1: Picrate Reagent
Reagent 2: Diluent Reagent
Reagent 3: Creatinine Standard (2 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Mix equal volume of Picrate and Diluent (1:1) to prepare desired volume of working reagent. Working reagent is stable for 6 months at 2 - 8 ^{0}C. The reagent kit should be stored at R.T. and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.200 O.D. against D/W at 505 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Creatinine
Reaction Type	Initial Rate (↑)
Wavelength	505 nm
Flow Cell Temp	37 °C
Blank setting	Reagent
Blank abs. limit	< 0.200

Reagent Volume	1000 µl
Sample Volume	50 µl
Incubation Temperature	37 °C
Delay Time	30 sec
Read Time	60 sec
Standard	2 mg/dL
Linearity	30 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum and heparinized plasma can be used. Sample should not be collected during PSB / BSB clearance test. Creatinine in the serum is stable for 2 days when stored at 2 - 8 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Sodium Picrate	7.7 mmol/l
Sodium Hydroxide	500 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Standard	Test
Reagent	1000 µl	1000 µl
Standard	50 µl	
Sample		50 µl
Mix the reagent and sample/standard in the above-mentioned ratio and start the stop watch.		
Aspirate reaction mixture into flow cell and measure the absorbance at 30th and 90th sec.		
NOTE: It is recommended to run creatinine standard with each assay.		

CALCULATION

$$\text{Creatinine (mg/dL)} = \frac{\Delta \text{ Abs/min of sample} \times 200}{\Delta \text{ Abs/min of standard}}$$

DETERMINATION OF URINE CREATININE

Creatinine determination in urine is usually carried out on a 24-hour urine sample. Thymol as preservative should be used for collection. The urine specimen should be thoroughly mixed and then diluted 1:25 with distilled water. Urine samples containing thymol as preservative are stable for one week at 2 - 8 ^{0}C.

PROCEDURE FOR URINE CREATININE ESTIMATION

Follow the same procedure as of serum creatinine estimation.

CALCULATION FOR URINE CREATININE ESTIMATION

$$\text{Urine Creatinine (mg/dL)} = \frac{\Delta \text{ Abs/min of sample} \times 2 \times 25}{\Delta \text{ Abs/min of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

	Serum Creatinine	Urine Creatinine
Male	0.7-1.4 mg/dL	21-26 mg/kg body weight/24 hrs
Female	0.6-1.2 mg/dL	16-22 mg/kg body weight/24 hrs

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.3 - 30 mg/dL. If the Creatinine value exceeds linearity limit (above 30 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Creatinine value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	2.25	0.11	5.0	2.48	0.1	4.2
High Value Serum	5.70	0.08	1.4	6.08	0.1	1.7

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Creatinine. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

If creatinine value exceeds 30 mg/dL then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct creatinine value.

BIBLIOGRAPHY

1. Henry R.J., et al, "Clinical Chemistry - Principles and Techniques" Harper & Row, II Ed (1974).
2. Larson K., Clin. Chem Acta. 41,209, (1972).

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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GMP
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