

LiquiMAX CREATININE- (End Point & Fixed Time) (MODIFIED JAFFE'S METHOD)

ORDERING INFORMATION

Ref. No.	Pack Size
AVCRE2 - 100	2 x 50 ml
AVCRE2- 200	4 x 50 ml
AVCRE2 - 200	2 x 100 ml

INTENDED USE:

LiquiMAX CREATININE is an in-vitro diagnostic kit for the quantitative determination of creatinine in human serum, plasma and Urine. This kit is a automated.

PRODUCT FEATURES :

- Both End Point & Fixed Time procedures.
- Three Liquid Reagents for End Point. (10 minutes End Point assay).
- Two Liquid Reagents for Fixed Time.(2 minutes Fixed Time assay)
- Working Reagent stability- 15 days at Room Temperature.
- With Lipid Clearing Factor (LCF).
- Linearity 25 mg/dl.
- Can be used on colorimeters and Semi-auto Analyzers.

CLINICAL SIGNIFICANCE : In muscle metabolism, creatinine is synthesized endogeneously from creatine and creatine phosphate. Under conditions of normal renal function, creatinine is excreted by glomerular filtration. Creatinine determinations are performed for the diagnosis and monitoring of acute and chronic renal disease as well as for the monitoring of renal dialysis. Creatinine concentrations in urine can be used as reference values for the excretion of certain analytes (albumin, α -amylase).

PRINCIPLE : END POINT

Picric acid in an alkaline medium reacts with Creatinine to form an Orange Colored Complex with the Alkaline Picrate.

Creatinine + Picric acid $\xrightarrow{\text{Alkaline Medium}}$ Orange Colored Complex (First Step)

Upon the addition of Acid Reagent in the Colorimetric End Point Procedure the orange colour complex formed above gets decolorized because of the pH change.

Orange Coloured Complex $\xrightarrow{\text{Acid Medium}}$ Yellowish decolorized complex (Second Step)

The extent of decolorization is directly proportional to the Creatinine concentration present in the serum sample where in the colour change between first step and second step is calculated

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.

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

STORAGE & STABILITY :

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

KIT COMPONENTS

- Picric acid Reagent R1
- Alkaline Reagent R2
- Acid Reagent R3
- Creatinine Standard : Concentration as stated on the label

COMPOSITION :

Picric acid	-	\geq	6.0 mMol/L
Sodium hydroxide	-	\geq	175 mMol/L
EDTA	-	\geq	1.8 mMol/L

Activators and stabilizers

REAGENT RECONSTITUTION & STABILITY

Mix one volume of Picric Acid Reagent with one volume of Alkaline Reagent in the empty bottle provided for working reagent preparation. The Working Reagent is stable for 15 days when stored in dark at Room Temperature.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance exceeds 0.4 at 505 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN :

- Unhemolysed Serum is the preferred Specimen.
- 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.

SYSTEM PARAMETERS : ONLY FOR ANALYZERS

Reaction Type	:	Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	:	Increasing
Sample Volume	:	50 μ l
Reagent Volume	:	1000 μ l
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.
Interval	:	90 sec
Low Normal	:	0.6
High Normal	:	1.5 (Males)

PROCEDURE : (FIXED TIME METHOD)

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

Reagent	(S)	(T)
Working Reagent	1.0 ml	1.0 ml
Standard (Conc. : 2 mg/dl)	50 μ l	--
Specimen	--	50 μ l

Mix well and 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 :

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

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

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

$$\text{Urine Creatinine / 24 hours} = \text{Urine Creatinine in gm/L.} \times 24 \text{ hours urine volume collected in litres.}$$

TEST PROCEDURE : (End Point Method) For 1 ml colorimeters.

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

Reagent	Standard (S)	Test (T)
Working Reagent	1.0 ml	1.0 ml
Creatinine Standard (Conc. 2 mg/dl)	100 µl	--
Specimen	--	100 µl
Mix well and keep at R.T. for 10 min. or at 37°C for 5 min. Read absorbance A_0 for S and T against distilled water at 520nm (500-520nm)		
Acid Reagent	50 µl	50 µl

Mix well and keep at R.T. for 5 min. Read absorbance A_1 for S and T against distilled water at 520nm (500-520nm)

$$\Delta A_S = A_{S_0} - A_{S_1}$$

$$\Delta A_T = A_{T_0} - A_{T_1}$$

CALCULATIONS :

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

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

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

$$\text{c) Urine Creatinine in gm/ 24 hours} = B \times 24 \text{ hrs urine volume collected in litres.}$$

EXPECTED VALUES :

	Serum	Urine
Males :	0.6 - 1.5 mg/dl	1.0 - 2.0 gm/24 hrs.
Females :	0.6 - 1.4 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.

QUALITY CONTROL & CALIBRATOR

To ensure adequate Quality Control, the use of commercial reference control serum is recommended with each assay batch. Use of Quality control material checks both, the instrument and the reagent performances.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 25 mg/dl

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.2 mg/dl

3. Interferences

No significant interference was observed from Bilirubin upto 25 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl, Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. Precision:

Intra-Assay

Sample	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	2.21	0.13	1.59
Control serum 2	5.31	0.32	2.15
Control serum 3	11.34	0.58	1.95

Inter-Assay

Sample	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	2.23	0.033	1.49
Control serum 2	5.41	0.035	1.32
Control serum 3	11.42	0.031	0.80

5. Method Comparison:

A comparison of the LiquiMAX Creatinine with a commercial obtainable assay (x) gave the following result : $y = 1.113x - 0.278$; $r = 0.990$

LIMITATIONS

Measuring range: 0.2-25 mg/dl. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2). Analytical sensitivity (lower detection limit): Detection limit: 0.2 mg/dl

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














NOTES :

- 1) If the Creatinine value exceeds 25 mg/dl dilute the specimen with equal volume of distilled water and reassay. 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.
- 4) In the End Point Method after the addition of Acid Reagent in Test (T) there may be slight haziness which disappears on thorough mixing.
- 5) Alkaline Reagent may solidify at places where the ambient temperature is below 10°C. In such cases keep the reagent at 37°C till it liquefies and then use.

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.

Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



Manufactured in India by :
AVECON™ Healthcare Pvt. Ltd.
Transforming Research into Innovations