LiquiMAX CREATININE - SLR

MODIFIED JAFFE'S METHOD

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVCRE1 - 100	4 x 25 ml	Single Liquid Reagent
AVCRE1 - 300	6 x 50 ml	
AVCRE1 - 500	10 x 50 ml	

INTENDED USE:

LiquiMAX CREATININE is an in-vitro diagnostic kit is use for the quantitative determination of creatinine in human serum, plasma and urine.

PRODUCT FEATURES :

1. Single Liquid Reagent.
2. 2 minutes fixed time assay (30 sec Delay +90 sec Interval).
3. Linearity 25 mg/dl.
4. With Lipid Clearing Factor (LCF).
5. Can be used on any discrete semi automated and automated 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, a-amylase).

PRINCIPLE:

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:

Liquimax-Creatinine-SLR 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

KIT COMPONENTS

1. Creatinine Reagent
2. Creatinine Standard : Concentration as stated on the label

COMPOSITION:

Picric acid	-	⩾ 10.0 mmol/L
Sodium hydroxide	-	⩾ 200 mmol/L
Activators and stabilizers		

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

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 if 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:

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

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	:	1.5 (Males)

TEST 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 mg/dl)	100 µl	-
Specimen	-	100 µl

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)

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

EXPECTED VALUES:

		Serum	Urine in 24 hours collection
Males	:	0.6 – 1.5 mg/dl	1.1 – 3.0 gm
Females	:	0.6 – 1.4 mg/dl	1.0 – 1.5 gm

It is recommended that each laboratory should establish its own normal range representing its patient population.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.
Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:
a) When using a new reagent or lot.
b) When QC values are out of range.

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 (N=20)	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 (N=20)	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-SLR (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113\,x - 0.278$; $r = 0.990$

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 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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	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		

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