Creatinine Test Kit

REF	Pack Size	Reagent 1	Reagent 2	Reagent 3 (Std)
CRTLMS01	2×50 ml	1×50 ml	1×50 ml	1×3 ml
CRTLMS02	4×50 ml	2×50 ml	2×50 ml	1×3 ml

INTENDED USE
Creatinine is use to quantitative estimation of creatinine in human serum or plasma.

CLINICAL SIGNIFICANCE
Creatinine has been found to be a fairly reliable indicator of kidney function. Elevated creatinine levels signify impaired kidney function or kidney disease. As the kidneys become impaired for any reason, the creatinine level in the blood will rise due to poor clearance of creatinine by the kidneys

METHOD
Jaffe, Alkaline Picrate Method, Two Point reaction

TEST PRINCIPLE
Creatinine forms a colored complex with picrate in alkaline medium. The rate of formation of the complex is measured.

KIT CONTENTS /COMPONENTS
Reagent 1: Alkaline Reagent
Reagent 2: Picric Acid
Reagent 3: Standard 2mg/dl

MATERIAL REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3.Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION, STORAGE AND STABILITY
1.Reagent 1, 2 are ready to use and are stable up to expiry date when stored at room temperature.
2.Upon opening of kit, store Reagents R1 and R2 at 15-30°C and Standard at 2-8°C. Stability since first opening of vials: within 60 days at 2-8°C.
For working reagent formation, Mix well one part of Reagent 1 and one part of Reagent 2. i.e. (500 µl R1 + 500 µl R2).

REAGENT DETEREORATION
Keep the Standard vial plugged after use, in order to avoid deterioration.

SPECIMEN
Serum(preferred) plasma (heparinate). Avoid severely hemolysed specimen collection. Samples are stable for 7 days at 2-8°C & 3 Months when frozen.

PROGRAM

Reaction Mode	Fixed time
Wavelength	505 nm (490 – 510 nm)
Light Path	10 mm
Reagent Volume	1000 µl
Sample Volume	100 µl
Delay Time	30 seconds
Read Time	90 seconds
Standard Conc.	2 mg / dl
Linearity	20 mg / dl

PROCEDURE

Addition Sequence	Standard	Sample
Reagent volume	1000 µl	1000 µl
Standard	100 µl	------
Sample	------	100 µl

Mix well and read the initial absorbance A1 for the standard and test after exactly 30 second, read another absorbance A2 of the standard and test exactly 90 sec. at 505nm. Calculate the change in the absorbance ΔA for both the standard and test.
A sample = A2 of sample – A1 of sample
A standard = A2 of standard – A1 of standard

CALCULATION
Concentration (C) of the creatinine in serum / plasma:

$$C = \frac{\text{Abs sample}}{\text{Abs standard}} \times 2 \text{ mg/dl (conc. Of std.)}$$

NORMAL VALUES
Men: 0.6 – 1.5 mg/dl
Women: 0.5 – 1.3 mg/ dl

LIMITATIONS
If the value exceeds 20 mg / dL, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION
It is suggested to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator or the Standard included, calibrate the assay.

WASTE DISPOSAL
This Product is made to be used in professional laboratories.

HIGHLIGHTS
1.Storage condition mentioned on the kit is to be used.
2.Before testing bring the reagents to the R.T.
3.Avoid reagents contamination.
4.Every time use new pipette-tips for pipetting out the reagents.
5.These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCE
Tietz N.W., ed. Clinical Guide to laboratory Tests, 3rd ed. Philadelphia, Pa: W.B. Saunders,1995:186,188
Lords Data File.

REF	Catalog No.	Σ	Contain Sufficient for test
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/CRT/01 Rev.: 02; Rev Dated.: 22/07/2024

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