# Creatinine Test Kit

| REF | Pack Size | Reagent 1 | Reagent 2 |
|---|---|---|---|
| CRTLMB01 | 1 x 70 + 1 x 70 | 1 x 70 | 1 x 70 |

## 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

## MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

## 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.
3.Upon opening of kit, store Reagents R1 and R2 at 15-30 °C and
For working reagent formation, Mix well one part of Reagent 1 and one part of Reagent 2.

## ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

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

## APPLICATION For LM1016-400 TPH

| | |
|---|---|
| Method | Two Point |
| Primary filter | 510 |
| Secondary filter | No |
| R1 Volume | 150 |
| R1 Position | * |
| Incubation time (Sec) | 30 |
| R2 Volume | 150 |
| R2 Position | * |
| Incubation time (Sec) | - |
| Sample Volume | 30 |
| Read Time | 90 |
| Calibrator Concentration | As on vial label |
| Mix speed set | Middle |
| Unit | mg/dl |
| Decimal | 2 |

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## CALIBRATION
**For calibration, it is recommended to use any multi calibrator.**

## CALCULATION
Calculations Fully automated systems automatically calculate the creatinine concentration of each sample

## 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.

## SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

## QUALITY CONTROL AND CALIBRATION
It is recommended 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 multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

## PRECISION
**Reproducibility was determined using quality control sera as shown below**

| | Intra run | | Inter run | |
|---|---|---|---|---|
| Control | Level 1 | Level 2 | Level 1 | Level 2 |
| n | 20 | 20 | 20 | 20 |
| Mean (gm/dl) | 1.45 | 3.83 | 1.45 | 3.89 |
| SD | 0.007 | 0.07 | 0.004 | 0.06 |
| CV (%) | 0.004 | 0.01 | 0.002 | 0.01 |

## WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

## REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

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

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