CREATININE-SL
(JAFFE'S Kinetic Method)

DIATEK

CLINICAL SIGNIFICANCE :

As a measure of kidney function, clinically the estimation of serum creatinine is considered superior to that of blood urea nitrogen, and the determination of the endogenous creatinine clearance is the commonly employed clinical measure of glomerular filtration rate. Creatinine is the catabolic product of creatinine phosphate, which is used by the skeletal muscle. The daily production depends on muscular mass and it is excreted out of the body entirely by the kidneys. Increased levels are found in renal dysfunction, reduced renal blood flow (shock, dehydration, congestive heart failure). Decreased levels are found in muscular dystrophy.

TEST PRINCIPLE :

Creatinine + Sodium Picrate $\xrightarrow{\text{Alkaline Medium}}$ Creatinine Picrate Complex (yellow to orange)

Creatinine in the samples reacts with the picric acid in alkaline buffer solution to form a water soluble red compound, the colour intensity of which is proportional to the concentration of creatinine in the sample. The rate of formation of a coloured complex compound between creatinine and alkaline picrate is measured. The effects of interfering substances are reduced through the Fixed Time procedure.

REAGENTS COMPOSITION :

Reagent 1 : Picric Acid 6.2 mmol/L ,Sodium Hydroxide 0.29 mmol/L, Solvent, Surfactants and Stabilisers pH 12.8 (±0.2)

Creatinine Standard : Concentration 2.0 mg/dL

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8 ºC, and contaminations prevented during their use. Do not use reagents over the expiration date. Once opened the reagent is stable for at least 1 months at 2 – 8 °C and 10 days on-board the auto analyzer at approximately10°C.

KIT CONTENTS

CODE No.	*CRSL01*
Pack size :	(2x50 mL)
Reagent 1 (R1) Creatinine SL Reagent :	2 x 50 mL
Creatinine Standard (2 mg/dl) :	2 mL

REAGENT PREPARATION:

Reagent is Ready-to-use

SAMPLES : Serum or Heparinised / EDTA Plasma and Urine

Serum should be separated from blood as soon as possible.
Urine sample to be diluted 1:20 with D. Water

MATERIALS REQUIRED BUT NOT PROVIDED :

Creatinine Control (Use of assayed QC sera is recommended to validate test result).

ASSAY CONDITIONS:

Wavelength : ..... 520 nm (500 - 530 nm)
Cuvette: ..... 1 cm light path
Constant temperature 37ºC
Reaction (Mode)..... Fixed Time
Standard Concentration..... 2 mg/dl
Delay ..... 30 sec
Read time..... 60 sec
Linearity..... 20 mg/dl
Unit..... mg/dl
Reaction Slope..... Increasing
Blanking..... D . Water

INTERFERENCES

Interferences are found according to the relevant literature.

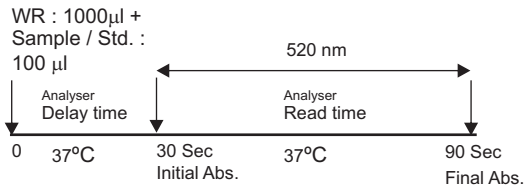
PROCEDURE :

Pipette into test tubes labeled Standard (S) and Test (T) as follows:

	S	T
Creatinine SL Reagent (R1)	1000µl	1000µl
Creatinine Standard	100µl	
Specimen		100µl

Mix and read the optical absorbance (A1) 30 seconds after the sample or standard addition. Exactly 60 seconds after the first reading take second reading (A2) at 37ºC.

Assay Procedure summary:



CALCULATIONS :

$$\text{Creatinine (mg/dL)} = \frac{\Delta \text{ Abs of Test}}{\Delta \text{ Abs of Standard}} \times 2 \text{ (Conc. of Standard)}$$

For Urine sample multiply the final result by corresponding dilution factor.

REFERENCE RANGE :

Female :	Serum: 0.5 -1.1 mg/dl	Urine: 1.0 - 1.8 gm/24h
Male :	Serum: 0.6 -1.2 mg/dl	Urine: 1.1 - 3.0 gm/24h

The above reference range is guideline and all the laboratories must establish their age and sex specific own normal reference range. Final diagnosis should be made with correlation of clinical factors.

PRECAUTIONS :

1. Storage conditions as mentioned on the kit to be adhered.
2. Use clean glassware and microtips while pipetting Reagents
3. Avoid contamination of the reagent during the assay process.
4. Before the assay begins, bring all the reagents to room temperature.
5. If a lesser volume of reagent is required for the absorbance reading, requisite volume can be taken in divisions, keeping the same ratio of reagent to specimen/standard.
6. Do not freeze or expose the reagents to high temperature and protect from direct sunlight as it will affect the performance of the kit.
7. Programmes for specific autoanalysers are available on request.
8. For accuracy of results, the assay procedure, reagent preparation and storage has to be meticulously followed.
9. Do not use reagent if the Reagent Blank OD exceds 1.0 against D. water at specified wavelength.
10. As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

LINEARITY AND DETECTION LIMIT :

The assay is linear upto Creatinine Concentration of 20 mg/dl. The results of the performance characteristics depend on the analyzer used. If the results obtained were greater than linearity limit, dilute the sample 1 : 4 with Normal Saline and multiply the result by 4.

BIBLIOGRAPHY

1. Butler AR. The Jaffé reaction. Identification of the coloured species. Clin Chim Acta 1975;59:227-32.

2. Vasiliades J. Reaction of alkaline picrate with creatinine. Kinetics and mechanism of formation of the monocreatininepicric acid complex. Clin Chem 1976;22:1664-71.

3.Newman, D. J., Price C. P., Non protein NitrogenMetabolite, in Tietz Fundamentals of Clinical Chemistry, 5th edition,Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 414.

Manufactured by : **DIATEK Healthcare Pvt. Ltd.**
P-54 , Phase-I , Kalyani Industrial Estate, Kalyani, Dist. : Nadia, Pin : 741235 E-mail : diatek@rediffmail.com
Corporate Office : P-27, Kalindi Housing Scheme, Kalindi, Kolkata- 700089, Help line : 033 - 25223075

Medical Device Insert / Kit Insert / Instruction for use (IFU)
CRSL/KI/01 1/10/2020 Rev:01