CREATININE

4 x 50 mL, 4 x 100 mL
51009001, 51009003

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of creatinine in serum, plasma & urine.

- Modified Jaffe's method
- Linear up to 24 mg/dL
- No Bilirubin interference up to 10 mg/dL

CLINICAL SIGNIFICANCE

Creatinine is formed in muscles from phospho creatinine. It is an important form of energy, being a store of high-energy phosphate. Creatinine determinations have one advantage over Urea determination that it is not affected by a high protein diet.

Serum creatinine is more specific & sensitive indicator of renal function. Simultaneous estimations of serum urea & creatinine provides better information. Serum urea nitrogen, creatinine ratio is > 15 in pre renal failure, & < 10 in renal failure.

Decreased levels are found in muscle dystrophy.

PRINCIPLE

Creatinine reacts with picric acid to produce a colored compound, creatinine alkaline picrate. The change in absorbance is proportional to the creatinine concentration.

REAGENT COMPOSITION

CREATININE BASE REAGENT (R1)	**2 x 50 mL, 2 x 100 mL**
Sodium hydroxide	300 mmol/L
Sodium Phosphate	25 mmol/L
CREATININE DYE REAGENT (R2)	**2 x 50 mL, 2 x 100 mL**
Picric Acid	8.73 mmol/L
Surfactant	
CREATININE STANDARD	**1 x 4 mL**
Creatinine standard concentration	2 mg/dL

STORAGE & STABILITY

The sealed reagents are stable up to the expiry date stated on the label, when stored at room temperature & standard at 2 - 8°C.

LINEARITY

This reagent is linear up to 24 mg/dL.

If the concentration is greater than linearity (24 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

NORMAL RANGE

It is recommended that each laboratory establish its own reference values.

The following value may be used as guide line.

Serum :	Men	: 0.7 – 1.4 mg/dL
	Female	: 0.6 – 1.2 mg/dL
Urine		: 0.80 – 1.80 gm/24 hour

PREPARATION AND STABILITY OF WORKING REAGENT

Mix 1 volume of Reagent 1 (R1) with 1 volume of Reagent 2 (R2).

PRECAUTION

To avoid contamination, use clean laboratory wares.

Avoid direct exposure of reagent to light.

SAMPLE

Serum / plasma (free of haemolysis) / Urine (diluted 1/100 with distilled water)

GENERAL SYSTEM PARAMETER

Mode of Reaction	Fixed time
Slope of reaction	Increasing
Wavelength	492 nm/ 505 nm
Temperature	37°C
Standard Concentration	2 mg/dL
Linearity	24 mg/dL
Blank	D I water
Delay time	60 sec
Interval	60 sec
Sample volume	100 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

LABORATORY PROCEDURE

	Standard	Sample
Working Reagent	1000 µL	1000 µL
Standard	100 µL	-
Sample	-	100 µL

Mix and read the optical density (T_1) 60 seconds after the sample or standard addition. Exactly 60 seconds after the first reading take second reading (T_2)

CALCULATION

$$\text{Creatinine conc. (mg/dL)} = \frac{(T_2 - T_1) \text{ of sample}}{(T_2 - T_1) \text{ of Standard}} \times 2$$

BIBLIOGRAPHY

1. Allen, L.C.; Clin chem. Vol.28 No.3, 1982, 555.
2. Haeckel, R., *et al.* ; Clin. Chem. 27/1 179-183 (1981).
3. Tanganelli, E., Prencipe,L. , Bassi, D., Cambiaghi, S. and Murador, E.; Clin.Chem 28/7, 1461-1464 (1982)

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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