

PRODUCT CODE
CS006

INTENDED USE

This reagent is intended for in vitro quantitative determination of Creatinine in serum & plasma.

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 provide better information. Serum Urea nitrogen, Creatinine ratio is > 15 in pre-renal failure, & < 10 in renal failure.

Decreased levels are found in muscle dystrophy.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

In the Jaffe reaction, Creatinine reacts with alkaline picrate to produce a reddish - orange color the intensity of which at 490 nm is directly proportional to the Creatinine concentration.



REAGENT COMPOSITION

Creatinine R1 (SL) Acid Reagent
Picric acid 35 mmol/L

Creatinine R2 (SL) Alkaline Reagent
Sodium Hydroxide 320 mmol/L

Creatinine Standard
Creatinine standard concentration 2 mg/dL or 177 μmol/L

REAGENT STORAGE AND STABILITY

The reagents are stable, if protected from light, up to the stated expiry date when stored at 15 - 25° C.

PREPARATION OF WORKING REAGENT

Mix 1 volume of Reagent 1(R1) with 1 volume of Reagent 2 (R2) Ensure working reagent is at 20-25°C before use. All reagents are stable until the stated expiry date when stored at 15-25°C and protected from direct sunlight. The working reagent is stable for about 32 hours at 15-25°C.

SPECIMEN

Serum is recommended, however heparinized plasma may also be used. Creatinine is stable for 24 hours at 2-8°C.

PRECAUTION

To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.

ASSAY

Wavelength : 490 nm
Cuvette : 1 cm light path
Temperature : 20-25°C (see note 2)
Measurement : Against air, increasing absorbance

PROCEDURE

Pipette into cuvettes	Blank	Standard	Sample
Working reagent	1000 μL	1000 μL	1000 μL
Standard	--	100 μL	--
Sample	--	--	100 μL

Mix well immediately in each case, simultaneously start the stopwatch. After 30 seconds measure absorbance A 1. Exactly 2 minutes after the measurement determine absorbance A2.
 $A2 - A1 = \Delta A$

CALCULATION

$$\text{Serum Creatinine (mg/dL)} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times 2 (\text{Std.conc.})$$

To convert mg/dL to μmol/L multiply by 88.4

Linearity

This reagent is linear up 13 mg/dL
If the concentration is greater than linearity (13 mg/dL), dilute the sample 1+5 with physiological saline (NaCl; 9g/L) and repeat the assay. Multiply the result by 6.

NORMAL RANGE

Serum Creatinine

Male	0.7-1.4 mg/dL	62-124 μmol/L
Female	0.7-1.2 mg/dL	62-106 μmol/L















QUALITY CONTROL

All control sera with Creatinine value determined by this method may be used.

NOTES

- The assay is not influenced by glucose 6g/l, bilirubin 20mg/l, ascorbic acid 10 mg/l, acetone 10mmol/L or acetoacetic acid 1 mmol/l.
- Reagent is highly dependent upon temperature, so a constant reaction temperature is required for both standard and sample within one series.
- Reagent 1 (picric acid) is a strong oxidizing agent avoid contact with skin. Wipe any spillages as picric acid is explosive.
- Reagent 2 (NaOH) is caustic. Do not swallow avoid contact with skin and mucous membrane.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

BIBLIOGRAPHY

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- Tietz, N.W. (Ed.); Textbook of Clinical Chemistry, W.B. Saunders, 1271 , 1986