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PARAMCARE™

Creatinine Test Kit
(Enzymatic Method)

Quantitative determination of Creatinine in human Serum / Plasma.
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
CRE 25	1 X 25 ml
CRE 50	1 X 50 ml
CRE 100	1X100 ml
CRE 5000	1X5000 ml
CRE 10000	1X10000 ml

CLINICAL SIGNIFICANCE
Creatinine is the catabolic product of high energy storage compound, Creatinine Phosphate formed in muscle. The amount of creatinine produced is fairly constant and is primarily a function of muscle mass. Creatinine is excreted out of body entirely by the kidneys.
Elevated levels are found in renal dysfunction, reduced renal blood flow (shock, dehydration, congestive heart failure) diabetes acromegaly. Decreased levels are found in muscular dystrophy.

Method
Enzymatic Method.

PRINCIPLE
Creatinine present in sample converted into creatine by creatinine amidohydrolase. The creatine produced is hydrolyzed to sarcosine and urea by creatinine amidinohydrolase. Next, the enzyme sarcosine, yielding glycine, formaldehyde and hydrogen peroxide. In presence of peroxidase, hydrogen peroxide react with N-ethyle-N-sulphopropyle-m-toluidine and 4-aminoantipyrine, yielding a quinoneimine. The color intensity of the reaction product is directly proportional to Creatinine concentration in sample.

REAGENT
Reagent 1 : Enzyme Reagent I
Reagent 2 : Enzyme Reagent II
Standard : 2 mg/dl.

REAGENT PREPARATION
Mix the reagent in the ratio of 600µl of R1 and 200µl of R2 and mix well.

REAGENT STORAGE AND STABILITY
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum, heparin plasma or EDTA plasma, Urine
Stability:
In serum /plasma: 7 days at 4 – 8°C
at least 3 months at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!
In urine: 1 day at 20 – 25°C, 6 days at 4 – 8°C
6 months at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!
Dilute urine 1 + 19 with dist. water; multiply the result by 20

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, Calibrator and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	546 nm
Reaction Temperature	37°C
Measurement	Against Reagent
Reaction	End point
Reaction Direction	Increasing
Sample Volume	20 µl
Reagent Volume	600 µl + 200 µl
Incubation	5 min + 5 min.
Linearity	25 mg/dl

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

	Blank	Standard	Sample
Reagent 1	600 µl	600 µl	600 µl
Sample	20 µl	20 µl	20 µl
Mix well and incubate for 5 min at 37°C and add			
Reagent 2	200 µl	200 µl	200 µl

Mix well and incubate for 5 min at 37°C. Measure the absorbance of sample and standard against reagent blank.

SAMPLE DILUTIONS
- This method is linear upto a concentration of 25 mg/dl.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION
Results are calculated, usually automatically by the instrument, as follows:

$$\text{Creatinine (mg/dl)} = \frac{\text{Sample Abs.}}{\text{Standard Abs}} \times \text{Standard Concentration}$$

LINEARITY
The method is linear upto a concentration of 25 mg/dl. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

REFERENCE VALUES

	MEN	WOMEN
SERUM	0.8 - 1.4	0.7 - 1.2 mg/dl
24h URINE	1.0 - 2.0	0.8 - 1.8 G/24h

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE
- Hemoglobin: No interference found upto 500 mg/dL.
- Lipemia: No interference found upto 1250 mg/dL.

- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

Henry, J.B, Young D.S. teitz N.W, Vasilades, J, Can. Chem (1972), 18.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	For *in vitro* Diagnostic use only
	Store between
	Manufacturer
	Keep away from sunlight

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