

CREATININE (Sarcosine oxidase method)

This kit is used for the in vitro determination of creatinine content in serum, plasma or urine.

REF: BS.1/CR02.025.0050

CLINICAL SIGNIFICANCE

Creatinine is formed in muscle from creatine phosphate by spontaneous and irreversible conversion, and the amount of creatinine formed is usually fairly constant unless there is a large change in muscle mass. Free creatinine is not reused in body metabolism but is mainly filtered through the glomerulus and subsequently excreted in the urine. The amount of creatinine circulating is therefore completely dependent on the rate of its excretion, and thus the measurement of creatinine in serum or plasma (usually performed together with a urea test) can be used to check kidney function as a diagnostic indicator of advanced kidney disease. An increase in creatinine is seen in chronic renal failure with reduced excretion or in acromegaly. The main clinical diagnostic methods of creatinine determination kit are picric acid method, creatinine deaminase method and creatine oxidase enzyme method.

METHOD PRINCIPLE

In the first step of the reaction, the endogenous creatine and sarcosine in the sample are eliminated with creatinase and sarcosine oxidase. In the second step of the reaction, creatinine in the sample is generated in the presence of creatinase to form creatine, which in turn generates hydrogen peroxide in the presence of creatinase and creatine oxidase, the latter forming a red quinonimine compound with 4-aminoantipyrine and TOOS by the action of oxidase, thus causing an increase in absorbance at 546 nm, such change being proportional to the concentration of creatinine in the sample.

REAGENT COMPOSITION

R1: HEPES Creatinase Sarcosine Oxidase Peroxidase TOOS	6 g/L 30 KU/L 15 KU/L 2 KU/L 0.4 g/L
R2: 4-Aminoantipyrine HEPES Creatinine Enzyme	0.4 g/L 50 g/L 240 KU/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment.

For further information, refer to the Creatinine reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien Creatinine reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C.

Deterioration

The **BioScien** Creatinine reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum or heparinized plasma.

Fresh serum or plasma (heparin or EDTA anticoagulated). Serum samples are stable at room temperature for 7 days.

Urines

fresh urine, urine specimens were diluted 1:10 times with saline (or distilled water, deionized water).

SYSTEM PARAMETERS

Wavelength	548 (530~560) nm
Optical path	1 cm
Assay type	Endpoint
Direction	Increase
Sample Reagent Ratio	1:4
Incubation Time	10 minutes at 37 °C
Temperature	37°C
Zero adjustment	Reagent blank
Sensitivity	54 µmol/L
Linearity	8850 µmol/L

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Standard	Specimen
R1	240 µl	240 µl
	6 µl	-
Specimen	-	6 µl
Mix. Let stands for 5 minutes at 37°C then add		
R2	80 µl	80 µl

Mix well, read the absorbance A2 after 5 min of reaction at 37°C and calculate $\Delta A = A2 - A1$.

CALCULATION

Serum, plasma

Creat. concentration (µmol/L) = $\frac{\Delta A(T) \text{ specimen}}{\Delta A(S) \text{ standard}} \times \text{Calibrator concentration}$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact **BioScien** technical support.

PERFORMANCE CHARACTERISTICS

The results of the performance characteristics depend on the analyzer used.

Precision

repeatability CV ≤ 5%; relative extreme difference between batches ≤ 10%.

Accuracy

Relative deviation ≤ 10%.

Sensitivity

0.990 µmol/L

Linearity

should not exceed 7 µmol/L

INTERFERING SUBSTANCES

Haemoglobin

No interference from haemoglobin

Bilirubin

No significant interference from free bilirubin

lipemia

No significant interference.

Anticoagulants

Complexing anticoagulants such as citrate, oxalate and EDTA must be avoided.

REFERENCE VALUES

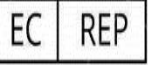
Serum or plasma	µmol/L
Adult (Male)	59-104
Adult (Female)	45-84 µmol/L

Morning urine	µmol/L
Adult (Male)	3540-24600
Adult (Female)	2550-20,000

REFERENCES

1. Newman DJ, Price CP. Renal function and nitrogen metabolites. in: Burtis CA, Ashwood ER, editors. *tietz Textbook of Clinical Chemistry*. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-.
2. Thomas L. *Clinical Laboratory Diagnostics*. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.

SYMBOLS IN PRODUCT LABELLING			
	For in-vitro diagnostic use		Number of <n> test in the pack
	Batch Code/Lot number		Caution
	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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