

CREATININE

Sarcosine Oxidase method
Liquid Reagents ready to use

REF 13200160 R1 8X20mL
REF 13201040 R2 8X5mL

IVD

PRODUCT CODE: CRE-8D25

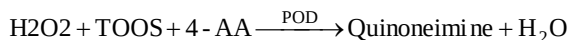
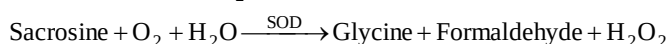
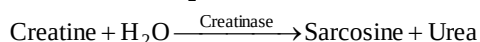
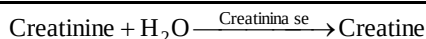
INTENDED USE

Quantitative determination of Creatinine in serum, plasma and urine.

CLINICAL SIGNIFICANCE

Creatinine is a byproduct of the breakdown of creatine, and the amount endogenously produced is proportional to an individual's muscle mass; therefore, its production varies with age and sex. The Creatinine produced is released into the blood, and elevated levels may indicate acute or chronic renal failure, or cases of dehydration.

PRINCIPLE



SAMPLE

Serum, plasma with heparin, urine 24h, diluted 1:100 with saline.

Do not use hemolyzed samples.

Creatinine in the samples is stable 24 hours at 2-8°C.

Freeze the sample for longer periods.

KIT COMPONENTS

Reagent (1) CREA Volume = 20/160ml	TOOS Creatinase SOD POD	1 mmol/l 30kU/L 14kU/L 800U/L	
Reagent (2) CREA Volume = 5/40ml	Creatinase 4-AA	300kU/L 2.5mmol/L	!
Standard Volume = 5 ml	Creatinine derivative	Value on label	

The reagents are stable until the expiration date indicated on the label when stored at 2-8°C. Do not use beyond the expiry date. Once opened, the reagents are stable for 28 days at 2-8°C if contamination is avoided. Keep bottles tightly closed when not in use.

REAGENT PREPARATION

Reagent 1 (R1) and Reagent 2 (R2) are ready to use. Mix gently before use. Do not mix R1 and R2 together. Use the required quantities according to the number of tests to be performed.

PRECAUTIONS AND WARNINGS

Reagents may contain some non-reactive and preservative components. Use the normal precautions required in the laboratory. Dispose of waste according to local laws.

PROCEDURE

Wavelength: 546 nm (540 – 560)
Lightpath: 1 cm
Temperature: 37°C
Reading: against distilled water
Method: Increasing Kinetic
Sample/Reagent: 1/4

pipette:	sample
Reagent 1	240 µl
sample	6 µl
Mix and after 5 minutes add	
Reagent 2	60 µl

Mix, incubate at 37°C for 5 minutes, and read the absorbance of the sample (Ax1) and standard (As1). After exactly one minute from the first reading, read the absorbance of the sample (Ax2) and standard (As2).

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R1 and R2 are for in vitro diagnostic use only. Avoid contact with skin, eyes, and mucous membranes. Do not ingest. Handle all reagents and specimens according to appropriate laboratory safety practices. Keep reagent bottles tightly closed when not in use.

RESULTS CALCULATIONS

Serum/plasma:

$$\text{Creatinine mg/dl} = (\text{Ax2} - \text{Ax1}) / (\text{As2} - \text{As1}) \times \text{Standard Value}$$

Urine 24h: Creatinine mg/24h =

$$= (\text{Ax2} - \text{Ax1}) / (\text{As2} - \text{As1}) \times \text{Std Value} \times 100 (\text{dilution}) \times \text{diuresis (dl)}$$

Clearance creatinine (ml/min)=

$$= \frac{\text{creatinine urine (mg/dl)} \times [\text{diuresis (ml)} / 1440]}{\text{Creatinine serum (mg/dl)}}$$

Conversion factor: mg/dl x 88,4 = µmol/l

EXPECTED VALUES

Serum, plasma:

Men: 0.62– 1.15 mg/dl (55 – 102 µmol/l)
Women : 0.44 – 0.89 mg/dl (39 – 79 µmol/l)

Urine:

Urine(24h):

Men: 14–26 mg/kg/24h (124–230 µmol/kg/24h)
Women: 11–20 mg/kg/24h (97–177 µmol/kg/24h)

Clearance:

Men: 88.0–176.4 mL/min

Women: 75.7–173.0 mL/min

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 0.4 mg/dl.

Linearity: the method's linearity was tested up to 24 mg/dl. For higher values, dilute the sample 1:2 and multiply the result by 2.

Precision intra-assay:

	Level 1	Level 2
Mean (mg/dl)	1.22	3.76
SD	0.012	0.017
CV %	1.01	0.46

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	1.25	3.81
SD	0.011	0.021
CV %	0.85	0.54

Interferences: Ascorbic acid up to 100 mg/dl does not interfere. bilirubin does not interfere up to 5 mg/dl. A hemoglobin concentration greater than 100 mg/dl increases the reading. Glucose up to 500 mg/dl does not interfere.

Correlation against a reference method:

$$Y = 0.9294x + 0.16 \quad r = 0.9998$$

REFERENCES

- Jaffè M., Z. Physiol. Chem., 10:391 (1886).
- Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989
- Young, D.S., et al. Clin. Chem. 21:1D (1975).

