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CREATININE ENZYMATIC

CE

STABLE LIQUID REAGENT

Cat. No.:	46161,46161S	46162,46162S	46163
	120 ml	500 ml	10x20 ml
	(1x90 ml+1x30ml)	(1x375 ml +1x125 ml)	(10x15 ml+ 10x5 ml)

Reagent kit for determination of creatinine concentration in serum and urine. Colorimetric, enzymatic test.

Creatinine is released during metabolism of creatine phosphate, and is excreted by the kidneys. Creatinine concentration in blood and in urine represents a primary indicator for renal function, especially that for glomerular filtration. Increased levels are associated with acute renal impairment, chronic nephritis, obstruction of the urinary tract, strong physical overloading. Low creatinine concentrations are found in conditions with juvenile diabetes mellitus, pregnancy and muscular dystrophy.

Principle

$$Creatinine + H_2O \xrightarrow{\text{Creatininase}} Creatine$$

$$Creatine + H_2O \xrightarrow{\text{Creatinase}} Sarcosine + Urea$$

$$Sarcosine + O_2 \xrightarrow{\text{Sarconise oxidase}} Glycine + HCHO + H_2O_2$$

$$H_2O_2 + TOOS + 4\,Aminoantipyrine \xrightarrow{\text{Peroxidase}} Red\ quinone + 4H_2O$$

TOOS=N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl)m-Toluidine

Reference values
Serum creatinine:

	Male:	**53-100 µmol/l (0,6-1,13 mg/dl)**
	Female:	**40-88 µmol/l (0,45-1,00 mg/dl)**
Urine:		**7-16 mmol/24 h (0,08-0,18 mg/dl/24h)**

It is recommended that each laboratory should assign its own normal range.

Reagents

1. Reagent (R1)

Creatininase	>20 kU/l
Sarcosine oxidase	>6 kU/l
Ascorbate oxidase	>2 kU/l
Catalase	>100 kU/l
TOOS	>0,40 mmol/l

2. Reagent (R2)

4-aminoantipyrine	>2,5 mmol/l
Creatinase	>250 kU/l
Peroxidase	>50 kU/l

3. Creatinine standard
Ready for use.For details please check the insert.
Available only in Cat. No.: 46161S and 46162S

Precaution
Discard cloudy reagent. Avoid contamination by using clean laboratory materials (pipettes, plastic vials , ...) for analyzers.

Samples

Serum free of haemolysis. Urine diluted in ratio of 1:100 with distilled water.

PROCEDURE

Working reagent
The reagents are ready for use. If the absorbance of reagent 1 is higher than 0.01 or the absorbance of the reagent 2 is higher then 0.015 at 546 nm the reagent can not be used.

Assay conditions

Wavelength:	555 (540-570) nm
Temperature:	37 °C
Cuvette:	1 cm light path
Read against:	distilled water
Method:	endpoint (increasing)

Pipette into cuvette

	Blank	Standard	Sample
R1	1 ml	1 ml	1 ml
Distilled water	45µl		
Standard		45µl	
Sample			45µl

Mix and read the absorbance (Al) after a 5-minute incubation then add:

R2	330 µl	330 µl	330 µl

Mix and read the absorbance (A2) after a 5-minute incubation.

Calibration: (37°C, enzymatic, colorimetric method)
S1: Distilled water
S2: Creatinine standard Cat. No.: 50911 or
Roche C.F.A.S. (Calibrator for automated system)
Randox Calibration Serum Level I or
Randox Calibration Serum Level II
Calibration frequency:
Two point calibration is recommended
- after reagent lot change,
- as required following quality control procedures.

Calculation

$$\frac{(A2-A1)_{sample}}{(A2-A1)_{standard}} \times C_{standard} = C_{sample}$$

A = Absorbance
C = Concentration

Quality control
A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus 600 analyzer (37°C).

Linearity
The test is linear up to 1770 µmol/l (20 mg/dl).

Sensitivity
It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. Under manual conditions however, a change of 0.001 Abs is equivalent to 2.2 µmol/l (0,025mg/dl) creatinine concentration at 546 nm.

Precision

	Reproducibility		
	Average concentration (µmol/l)	SD	CV%
Sample I	112	0.94	0.84
Sample II.	352	3.48	0.99

	Repeatability		
	Average concentration (µmol/l)	SD	CV%
Sample I	99	1.08	1.09
Sample II.	157	1.31	0.83

Correlation
Comparative studies were done to compare our reagent with another commercial Creatinine Jaffe reagent.
The results from these studies are detailed below.
Correlation coefficient: r =0.9988
Linear regression: y (µmol/l)= 1.05x-14.60
(x= other commercial reagent, y= own reagent).

Specificity

Bilirubin 684 µmol/l (40 mg/dl), ascorbic acid 1136 mg/dl (11,36 mmol/l) and haemoglobin 80 µmol/l (500 mg/dl) don't interfere with the assay up to the given levels.

Note
Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For *in vitro* diagnostic use only.

The following symbols are used on labels

IVD For in vitro diagnostic use

Use by (last day of the month)

Temperature limitation

LOT Batch Code

REF Code

Bibliography
Artiss J.D., Mc Enroe R.J., Zak B., Clin. Chem. 30, 1389, 1984;