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CREATININE ENZYMATIC

CONCENTRATED LIQUID REAGENT

CE

Order information:

Catalogue number	Size
9571C	10 x 60 + 10 x 20 ml
9572C	4 x 60 + 4 x 20 ml

Reagent kit for quantitative in vitro determination of creatinine in serum and plasma.

Summary

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.

Method

Enzymatic PAP

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

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatinase}} \text{sarcosine} + \text{urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosin oxidase}} \text{glicyne} + HCHO + H_2O_2$$

$$4H_2O_2 + \text{TOOS} + \text{4-aminoantipiryne} \xrightarrow{\text{Peroxidase}} \text{red quinone dye} + 4H_2O$$

Reagents

Composition and concentrations

Reagent 1	
Creatinase	>60 kU/l
Sarcosine oxidase	>18 kU/l
Ascorbate oxidase	>6 kU/l
Catalase	>300 kU/l
TOOS	>1,2 mmol/l
Reagent 2	
4-aminoantipiryne	>7,5 mmol/l
Creatininase	>750 kU/l
Peroxidase	>150 kU/l

Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze!
Onboard stability after opening and the frequeny of calibration is 72 days.

Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

Preparation

The reagent is ready for use.

Sample

Serum, heparin, citrate or EDTA plasma.

Stability in serum:	7 days at 4 – 25°C
	3 month at -20°C
in urine:	2 days at 20 – 25°C
	6 days at 4 – 8°C
	6 month -20°C

Expected values and reference range

Serum, female:	37,7 – 85 µmol/l
male:	51 – 97 µmol/l
Urine:	6,9 – 15,8 mmol/l/24h

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

Assay procedure

Wavelength:	546 nm / 700 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against reagent blank
Reaction:	endpoint, increasing

	vak	sample or standard
reagent 1	300 µl	300 µl
dist. water (diluent)	600 µl	600 µl
dist. water (blank)	40 µl	-
sample or standard	-	40 µl
Mix and incubate for 5 minutes		
reagent 2	100 µl	100 µl
dist. water (diluent)	200 µl	200 µl
Mix and incubate for 5 minutes and read the absorbance against against blank.		

Calculation

Creatinine[µmol/l]=ΔA sample/ΔA standard × standard concentration[µmol/l]

Conversion factor

[µmol/l]=[mg/dl]×88,42

Calibration and quality control

S1: Distilled water
S2: Creatinine standard Cat.: 50911 or
Roche C.F.A.S. (Calibrator for automated system) or
Randox Calibration Serum Level I or
Randox Calibration Serum Level II
Calibration is recommended:

- after opening new reagent batch
- after system maitenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Preformance characteristics

Measuring range

The method is linear in the range 8 – 8000 µmol/l

Interferences

No significant intereference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 12 mmol/l, hemoglobin up to 0,8 g/l and ascorbate up to 2 g/l. Significant interference: >10%.

Limit of detection

The limit of detection is 0,58 µmol/l

Precision

Repeatability	mean	SD	CV
n = 20	[µmol/l]	[µmol/l]	[%]
normal sample	119	1,25	1,05
pathological sample	391	3,71	0,95
Reproduceability	mean	SD	CV
n = 10	[µmol/l]	[µmol/l]	[%]
normal sample	120	1,18	0,99
pathological sample	395	5,6	1,42

Method comparison

Comparison with the non-concentrated reagent.
analyser: Advia 2400
number of samples: 108
range: 35 – 1416 µmoll
correlation coefficient: 0,999
regression line equation: y = 0,992x - 1,969
(x= normal reagent, y= concentrated reagent)

For in vitro diagnostic use only!

The following symbols can be used on the labels

IVD	In vitro diagnostic device
	Manufacturer
CE	CE-marking
	Temperature limitations
	Use by (year/month)
LOT	Batch code
REF	Catalogue number
	This way up
	Biological risk

Literature

Artiss J.D., Mc Enroe R.J., Zak B., Clin. Chem. 30, 1389, 1984;
Tietz Clinical Guide To Laboratory Tests, 4th edition, Elsevier, 2006