

Cat. No.:	41751,41751S	41752,41752S	41753
	1x500 ml	10x500 ml	10x40 ml
	(1x250 ml+1x250 ml)	(10x250ml+10x250ml)	(10x20 ml+10x20 ml)

Reagent kit for the determination of creatinine concentration in serum and urine. A colorimetric, alkaline picrate method (Jaffé).

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 forms with alkaline picrate (in ratio of 1:1) a colored creatinine picrate complex containing ionic bonds. The rate of formation of the colored complex is proportional to the creatinine concentration.

Reference values

Serum:	Male:	62-115 µmol/l (0,70-1,30 mg/dl)
	Female:	44-106 µmol/l (0,50-1,20 mg/dl)
Urine:		7-16 mmol/24h (0,08-0,18 mg/dl)

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

Reagents

1. Reagent (R1)

Sodium hydroxyde	400 mmol/l
Disodium phosphate	25 mmol/l

2. Reagent (R2)

Picric acid	17.5 mmol/l
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3. Creatinine standard

Ready for use. For details please check the insert.
Available only in Cat. No.: 41751S and 41752S

Safety instructions:

Reagent 1:

X, Irritant
R36/38 Irritating to eyes and skin
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Reagent 2:

R1 Explosive when dry

Samples

Serum and 12 h or 24 h collected urine, resp. Urine must be diluted in ratio of 1:100 with distilled water.

PROCEDURE

Preparation of working reagent

Mix (R1) with (R2) in a ratio of 1:1.

Stability of working reagent

at: 20-25 °C 1 month

If the absorbance of working reagent is higher than 0.4 at 492 nm the reagent can not be used.

Assay conditions

Wavelength:	492 (480-520) nm
Temperature:	37 °C
Cuvette:	1 cm light path
Method:	kinetic (increasing)

Pipette into cuvette

	Standard	Sample
Standard	100 µl	
Sample		100 µl
Working reagent	1 ml	1 ml

Mix and after 30 seconds read the absorbance against distilled water (A1). After 2 minutes incubation read the absorbance again (A2).

The reagent kit is suitable for two-reagent method, too. Reagents (R1) and (R2) can also be pipetted separately (0.5-0.5 ml).

Calibration: (37°C, Jaffé method)

S1: Distilled water
S2: Creatinine standard Cat. No.: 50911 or Roche C.F.A.S. (Calibrator for automated system)
Randox Calibration Serum Level II

Calibration frequency

Two point calibration is recommended:
- after reagent lot change,
- as required following quality control procedures.

Calculation using calibration

$$\frac{A2_{sample} - A1_{sample}}{A2_{standard} - A1_{standard}} \times C_{standard} = C_{sample}$$

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

Relationship of absorbance vs concentration is linear up to 1326 µmol/l (15 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 units/min is equivalent to 3.82 µmol/l (0,04 mg/dl) creatinine concentration at 492 nm.

Precision

Sample	Reproducibility		
	Average concentration (µmol/l)	SD	CV%
sample I	110	0.98	0.88
sample II	338	3.36	0.99

Repeatability

Sample	Repeatability		
	Average concentration (µmol/l)	SD	CV%
sample I	78.4	0.75	0.96
sample II	236	8.98	3.81

Correlation

Comparative studies were done to compare our reagent with another commercial Creatinine reagent.

The results from these studies are detailed below.

Correlation coefficient: r=0.9994

Linear regression: y (µmol/l) = 0.987x + 8.523

(x= other commercial reagent, y= own reagent).

Specificity

Hemoglobin 6,2 µmol/l (40 mg/dl), bilirubin 68,4 µmol/l (4 mg/dl), lipid 1000mg/dl, glucose 2,8 mmol/l (50mg/dl) and ascorbic acid 0,85 mmol/l (15mg/dl) don't interfere with the assay up to the given levels.

Note

The presence of high concentrations of keton derivatives, pyruvic acid, ascorbic acid, glucose, urea, proteins interfere with the test. Kinetic assay reduces the disturbing effects of some substances. Because of differences in reaction rates, it is advisable to take readings during the first few minutes of the reaction. Creatinine reacts faster with picrate as does with some non-specific disturbing chromogens.

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

 For in vitro diagnostic use

 Use by (last day of the month)

 Temperature limitation

 Batch Code

 Code

Bibliography

Bartel S.H.: Clin. Chim. Acta 37,193 (1972)