ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

CREATININE

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of concentration of Creatinine in serum, plasma or urine on photometric systems.

ORDERING INFORMATION

Pack Size	Cat No.
2 X 50 ml	CRJA 0250
4 X 50 ml	CRJA 0450
2 X 500 ml	CRJA 02 500

CLINICAL SIGNIFICANCE : Creatinine is a waste product excreted by the kidneys mainly by glomerular filtration. The concentration of creatinine in plasma of a healthy individual is fairly constant, independent from water intake, exercise and rate of urine production. Therefore increased plasma creatinine values always indicate decreased excretion, i.e. impaired kidney function. The creatinine clearance enables a quite good estimation of the glomerulor filtration rate (GFR) which allows better detection of kidney diseases and monitoring of renal function. For this purpose creatinine is measured simultaneously in serum and urine collected over a defined time period.

METHOD :
Kinetic test without deproteinization according to the Jaffe method.

PRINCIPLE :
Creatinine forms a colored orange-red complex in an alkaline picrate solution. The difference in absorbance at fixed times during conversion is proportional to the concentration of creatinine in the sample.

Creatinine + Alkaline Picrate ⟶ Creatinine picrate complex

REAGENTS :

COMPONENTS AND CONCENTRATIONS:

R1:
Picric Acid : 9 mmol/l

R2:
Sodium Hydroxide : 0.4 mol/l
Preservative & Stabilizer

Standard : 2 mg/dl (177 µmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial Label, if stored at 15 to 30°C and contamination is avoided. Do not freeze the reagents!

WARNINGS AND PRECAUTIONS :
1. Reagent 1 contains picric acid : Toxic by inhalation, in contact with skin and when swallowed. Wear suitable gloves and eye / face protection. After contact with skin, wash immediately with polyethylenglycol 400 (DAB 8) or plenty of water. If sickness occurs seek medical advice.
2. Reagent 2 contains sodium hydroxide : Irritating to eyes and skin, in case of contact with eyes rinse immediately with plenty of water and seek medical advice. Wear suitable gloves and eye/face protection. In case of accident or if you feel unwell seek medical advice immediately.
3. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The reagent and standard are ready-to-use.
Mix 1 parts of R1 + 1 part of R2, (e.g. 20 ml R1 + 20 ml R2) = Working Reagent
Stability of Working Reagent : 5 hours at 20 to 25°C.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Serum, heparinized plasma, urine.
Stability
in serum or plasma: 7 days at 4 to 25°C, at least 3 months at – 20°C
In urine: 2 days at 20 to 25°C, 6 days at 4 to 8°C, 6 months at – 20°C
Dilute urine 1 + 49 with dist. Water.
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.
Wavelength : Hg 492 nm, (490 or 510 nm)
Optical Path : 1 cm
Temperature : 37°C
Mode : Fixed Time / Initial Rate
Bring all the contents of the kit to Room Temperature prior to use.
Read rate of change of absorbance of sample during fixed time interval against distilled water.
Label the test tube as standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :
Prewarm working reagent at 37°C for 2 minutes.

	Standard	Sample / Control
Working Reagent	1000 µl	1000 µl
Standard	100 µl	—
Sample / Control	—	100 µl

Mix and read the variation of absorbance (ΔA) between 30 seconds and 90 seconds.

CALCULATION :
With standard or calibrator.

$$\text{Concentration in sample (mg/dl)} = \frac{\text{Concentration of Standard}}{\Delta \text{ A Standard}} \times \Delta \text{ A Sample}$$

CREATININE CLEARANCE :

$$\text{Creatinine Clearance ml/min} = \frac{\text{Urine Creatinine (mg/dl) X Urine Volume (in mL for 24 hrs)}}{\text{Serum Creatinine (mg/dl) x 1440 (Time in min. for 24 hrs)}}$$

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m^2).

CONVERSION FACTOR :
Creatinine [mg/dl] X 88.4 = Creatinine [µmol/L]

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :
The test has been developed to determine Creatinine concentrations within a measuring range from 0.2 to 20 mg/dl (17.7 to 1768 µmol/L). When values exceed higher limit of the range samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :
No interference was observed by Ascorbic Acid up to 30 mg/dl (1703.4 µmol/L), Hemoglobin up to 0.5 g/dl (5 g/L) and Lipemia up to 600 mg/dl (6.78 mmol/L) Triglycerides. Bilirubin interferes starting with a bilirubin concentration of 4 mg/dl (68.4 µmol/L). A list of drugs and other interfering substances with Creatinine determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 0.2 mg/dl (17.7 µmol/L)

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	1.81	0.01	0.83
Sample 2	7.61	0.03	0.47
Sample 3	4.13	0.02	0.53

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	7.54	0.13	1.73
Sample 2	4.14	0.06	1.59
Sample 3	6.02	0.07	1.22

METHOD COMPARISON :
A comparison between Robonik Prietest Creatinine (y) and a commercially available test (x) using 20 samples gave following results :
Linear Regression : y = 0.8777 x + 0.1324 mg/dl
Correlation Coefficient : r = 0.9988

REFERENCE RANGE :
Serum / Plasma
Men: 0.9 to 1.5 mg/dl (80 to 133 µmol/L) **Women:** 0.7 to 1.3 mg/dl (62 to 115 µmol/L)
Creatinine Clearance
Men: 14 to 20 mg/kg/24 h (1238 to 1768 µmol/24 h) **Women:** 11 to 20 mg/kg/24h (972 to 1768 µmol/L/24 h)
It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Allston, C.A., *Non protein nitrogenous compounds and renal function.* Clinical Chemistry: Concepts and Application, Anderson, S.C., Cockayne, S. (W.B. Saunders eds. Philadel-phia USA), (1993), 369.
2. Vasiliades, J., *Reaction of alkaline picrate with creatinine. 1. Kinetics and mechanism of formation of the mono-creatinine picric acid complex. Clin. Chem.*, (1976), 22, 1664.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION **prietest TOUCH**
Name : CREAT , Mod : FIX_T
Pri.: 510 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : mg/dl
Lag : 30 , Read : 90
Blk : N, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 2.0
Normal HI = 1.5
Normal LO = 0.7
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Init. OD : = 0.400 H
Max Delta : = 0.60
Rgnt. Linearity : 20
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	CREATININE
Reaction	Fixed Time
Reaction Slope	Increasing
Wavelength 1	510 nm
Temperature	37°C
Zero Setting	Distilled Water
Lag Time	30 seconds
Read Time	90 seconds
Standard Conc.	2
Units	mg/dl
Sample Volume	100 µl
Reagent Volume	1000 µl
Reference Range	0.7 to 1.5
Reagent Linearity	20
Initial OD	< 0.400
Max Delta	0.60

ROBONIK®
An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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