Creatinine (Jaffe modified method)

In-vitro Diagnostic reagent/kit for quantitative determination of Creatinine in serum/plasma and urine sample on Photometric System.

Reagent
Reagent 1: Alkaline Solution
Reagent 2: Picric Acid Solution
Standard: Creatinine (Conc. 2 mg/dL)

Principle
Creatinine forms a colored complex with picrate in alkaline medium. The rate of formation of the complex is measured photometrically.

Summary
Creatinine is filtered by kidneys as waste product. Thus the concentration of creatinine in blood/serum of a normal individual is fairly constant. Therefore, increased blood/serum creatinine values always indicate decreased excretion meaning impaired kidney function. The creatinine concentration enables a quite good estimation for the 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.

Storage Instructions and Reagent Stability
The reagents and standard are stable till the date of expiry, if stored at 2°C-30°C, protected from light and contamination is avoided.
Do not freeze the reagents.

Composition
Reagent – Picric acid - 9 mmol/L, Sodium hydroxide - 0.4 mol/L.
Standard – Creatinine 2 mg/100mL

Waste Management
Please refer to local regulatory requirements.

Reagent Preparation
Mix 1 part of reagent 1 (R1) + 1 part reagent 2 (R2) = Working reagent. The working reagent is stable for 5 days at 2°C–25°C when stored in dark bottle.
The working reagent must be protected from light.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Specimen
Serum, heparin plasma or EDTA plasma Stability:

In Serum/Plasma	7 months at 2° – 8°C,
	3 months at -20°C
In Urine	6 Days at 2° – 8°C,
	3 months at -20°C

Dilute Urine 1 + 49 with distilled water
Discard contaminated specimens.

Assay Procedure

Wavelength	505 nm (490-510 nm)
Optical path	1 cm
Temperature	37°C

Sample/Standard	100 µL
Working reagent	1000 µL
Mix, incubate for 20 sec and read absorbance (A1) & exactly after another 60 sec (A2)	

Calculation
Calculation of the concentration "C" of Creatinine in serum or plasma.

$$C = 2.0 \times \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \text{ [mg/dL]}$$

Calculation of the concentration "C" of Creatinine in urine.

$$C = 2.0 \times 50 \times \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \text{ [mg/dL]}$$

$$\text{Creatinine clearance} = \frac{\text{(mg creatinine/dL urine) x (mL urine/24 hr.)}}{\text{(mg creatinine/dL serum) x 1440}} \text{ [mL/min]}$$

Quality Control
For internal quality normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions
1. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Wear suitable gloves and eye/face protection.
3. Always use safety pipettes to pull the reagents into a pipette.
4. Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
5. The reagents contain sodium hydroxide. Do not swallow. Avoid contact with skin and mucous membranes.
6. For professional use only!

Performance Characteristics Measuring Range
The test has been developed determine Creatinine activity from 0.20 mg/dL to 25 mg/dL. If such value is exceeded the sample should be diluted 1+9 with NaCl solution (9 g/L) and the result is multiplied by 10.

Linearity/Limit of Maximum Detection
The maximum limit of detection is 25 mg/dL.

Sensitivity/Limit of Detection
The lower limit of detection is 0.20 mg/dL.

Interferences
No Interferences was observed by Ascorbic acid up to 30 mg/dL, Bilirubin up to 4 mg/dL and Triglycerides up to 2000 mg/dL.

Precision

Intra assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	0.98	0.03	3.01
Sample 2	2.02	0.05	2.6
Sample 3	5.53	0.09	1.68

Inter assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	1.04	0.04	3.67
Sample 2	2.20	0.04	1.86
Sample 3	6.30	0.06	0.97

Method Comparison

A comparison of Precision Biomed Creatinine (y) with a commercially available test (x) using 20 samples gave following results:
$y = 0.960x + 0.031$; $r^2 = 0.991$.

Reference Range

Unit	mg/dL	µmol/L
Serum		
Men	0.7 - 1.4	53 - 97
Women	0.6 – 1.2	44 – 80
Urine		
Men	1 - 2 g / 24 hrs.	(8.84 – 17.7) mmol/24 hrs.
Women	0.8 – 1.8 g / 24 hrs.	(7.07 – 15.9) mmol/24 hrs.

for Creatinine Clearance

Unit	mL/min	mL/sec
Men	98 - 156	1.63 – 2.60
Women	95 - 160	1.58 – 2.67

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	Creatinine
Mode	Fixed time
Reaction slope	Increasing
Wavelength	505 nm
Path length	10 mm
Temperature	37°C
Standard conc.	2 mg/dL
Working Reagent	1 Part Reagent 1 (500 µL)
	1 Part Reagent 2 (500 µL)
Working Reagent volume	1000 µL
Sample volume	100 µL
Delay	20 Sec
Rate	60 sec
No. of readings	1 Nos.
Normal range	Men 0.7-1.4mg/dL
	Women 0.6 – 1.2 mg/dL
	Urine – 1 – 2 g/24 hours
Linearity	25 mg/dL
Sensitivity	0.20 mg/dL

Pack Size

Cat No.	Configuration	Pack
CRE00100	Reagent 1- 1 x 50mL Reagent 2 – 1 x 50mL Standard – 1 x 2mL	100mL
CRE01000	Reagent 1 - 1 x 500mL Reagent 2 – 1 x 500mL Standard – 1 x 4mL	1000mL

Literature

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2. Schirmeiste.J.et.al.(1964).Dtsch.Med.Wschr.89:1640
3. Mazzachi BC, Peake MJ, Ehrhardt V. Reference Range and Method Comparison Studies for Enzymatic and Jaffé Creatine Assays in Plasma and Serum and Early Morning Urine. Clin. Lab. 2000; 46: 53-55.
4. Swanson AF, Swartzentruber M, Nolen PA et al. Multicenter Evaluation of the Boehringer Mannheim Compensated, Rate-Blanked Creatinine/Jaffe Application on BM/Hitachi Systems. Advances in Clinical Diagnostics. 1993. Boehringer Mannheim Corporation.
5. Guder WG, Zawta B. Recommendations of the Working group on Preanalytical Quality of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine: The Quality of Diagnostic Samples. 1st ed Darmstadt: GIT Verlag 2001; p. 24-5,50-1.
6. Levey AS, Coresh J, Greene T, Marsh J et al: Expressing the Modification of Diet in Renal Disease Study Equation for Estimating Glomerular Filtration Rate with Standardized Serum Creatinine Values. Clin Chem 2007; 53 (4): 766-72.

Version : CRE/01

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

Plot No. – 193, "Silver Soil Industrial Park", Village – Anantpura- Chimanpura, Teh.- Chomu, District- Jaipur – 303702 (Rajasthan) India.

Ph. : +91-9982806050 Customer Care : +91-7820806050

E-mail : info@precisionbiomed.in, Website : www.precisionbiomed.in

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