Creatinine Single (JAFFE MODIFIED METHOD)

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

Labgene biotech

ORDER INFORMATION

Cat no.	Kit Information
LG111-100	Reagent - 2 x 50mL Standard – 1 x 2mL
LG111-1000	Reagent - 2 x 500mL Standard – 1 x 4mL

REAGENT

Reagent : Creatinine single Reagent
Standard: Creatinine (Conc. 2 mg/dL)

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.

PRINCIPLE

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

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.

REAGENTS AND COMPONENTS

Reagent – Picric acid - 16 mmol/L, Sodium hydroxide - 0.2 mol/L.
Standard – Creatinine 2 mg/100mL

WASTE MANAGEMENT

Please refer to local regulatory requirements.

WORKING REAGENT

Reagents are ready to use

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution 9 g/L.
General laboratory equipments.

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

Reagent	1000 µL
Standard	100 µL
Sample	100 µL

Mix, incubate for 30 sec and read absorbance (A1) & exactly after another 90 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

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

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

The test has been developed determine Creatinine activity from 0.20 mg/dL to 20 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 of the assay is 20.0 mg/dL.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection of the assay 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=25	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=25	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; r2 = 0.991.

REFERENCE RANGE

Unit	mg/dL (µmol/L)
Serum/Plasma	
Men	0.7 - 1.4 mg/dL (53 - 97 µmol/L)
Women	0.6 – 1.2 mg/dL (44 – 80 µmol/L)
Urine	
Men	1 - 2 g/Kg/24-h (8.84 – 17.7 mol/Kg/24-h)
Women	0.8 – 1.8 g/dL (7.07 – 15.9 µmol/L)
Creatinine Clearance	
Men	98 - 156 mL/min/ 1.63 – 2.60 mL/Sec
Women	95 – 160 mL/min/ 1.58 – 2.67 mL/Sec

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

ASSAY PARAMETERS

Mode	Fixed time
Reaction slope	Increasing
Wavelength	505 nm
Path length	10 mm
Temperature	37°C
Standard conc.	2 mg/dL
Reagent volume	1000 µL
Sample volume	100 µL
Delay	30 Sec.
Rate	90 sec.
Interval	30 Sec.
Normal range	Men 0.7-1.4mg/dL
Sample volume	Women 0.6 – 1.2 mg/dL
Delay	Urine – 1 – 2 g/24 hours
Linearity	20 mg/dL
Sensitivity	0.20 mg/dL

LITERATURE

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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.

INDEX OF SYMBOLS

ISO 13485	International Organization or Standardization		Keep out of Sunlight
	Manufacturer	IVD	For invitro diagnostic use only
	Expiry date		Read product insert before use.
LOT	Lot (batch) number		Do not use if package is damaged
2°C 8°C	Store between 2-8°c		Keep Away From Moisture

ART/IFU/PRC-111-02

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