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A Division of Orchard Medical

Creatinine Enzymatic

IVD

Order Information

Cat. No.	Kit Configuration
OMR1064	Reagent 1: 2 x 40 mL Reagent 2: 2 x 14 mL

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.

Method

Creatinine assay with Enzymatic method.

Principle

In the first reaction, creatinase and sarcosine oxidase were used in the enzymatic hydrolysis of endogenous creatine to produce hydrogen peroxide that is eliminated by catalase. In the second reaction, the catalase is inhibit red by sodium azide, and creatinase and 4- aminoantipyrine (4-AA) were added, and only the creatine generated from creatinine by creatininase was hydrolyzed sequentially by creatinase and sarcosine oxidase to produce hydrogen peroxide. This newly-formed hydrogen peroxide was measured in a coupled reaction catalyzed by peroxidase, with N- ethyl-n sulphopropyl-m toluidine (TOPS)/4-AA as a chromogen.

Reagent Storage Instructions and Stability

The reagents are stable till the date of expiry, if stored at 2°C-8°C, protected from light and contamination is avoided. Do not freeze the reagents.

Composition

Reagent - MOPS 90 mmol/L, Creatininase 30 KU/L, peroxidase 10 KU/L, Stabilizer and Preservative.
Standard: Creatinine 2 mg/dL.

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. Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
4. For professional use only!

Waste Management

Please refer to local regulatory requirements.

Reagent Preparation

Reagent 1 and 2 are ready to use.

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 days 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	546 nm (525 nm – 565 nm)
Optical path	10 mm
Temperature	37°C
Measurement	against Reagent blank

	Blank	Sample/Std./Calibrator
Reagent 1	450 µL	450 µL
Sample/Std./Calibrator	---	10 µL
Mix, Incubate for 5 min. at 37˚C then add		
Reagent 2	150 µL	150 µL
Mix and incubate 30 sec. measure absorbance A1 again after 5 minutes at 37°C. Measure the absorbance of sample A2 and the standard against the reagent blank.		

Calculation

Calculation of the concentration “C” of creatinine in serum or plasma.

Where, $\Delta A = A2 - A1$

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

$$C = 177 \times \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \text{ [µmol/L]}$$

Calculation of the concentration “C” of creatinine in urine.

$$C = 100 \times \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \text{ [mg/dL]}$$

$$C = 8.84 \times \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \text{ [µmol/L]}$$

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

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.

Performance Characteristics Measuring Range

The test has been developed to determine Creatinine activity from 0.01 mg/dL to 150 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.

Interferences

No Interferences was observed by Ascorbic acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 2000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 0.01 mg/dL.

Linearity

The higher limit of detection is 150 mg/dL.

Precision

Intra assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	1.65	0.02	1.48
Sample 2	4.80	0.05	1.05

Inter assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	2.24	0.07	2.94
Sample 2	7.64	0.07	0.86

Method Comparison

A comparison of Nucleus Diagnosys Creatinine Enzymatic (y) with a commercially available test (x) using 15 samples gave following results:
$y = 0.9461x + 0.0825$; $r^2 = 0.9899$.

Reference Range

Normal values for serum

	Unit mg/dL	µmol/L
Men	0.6 - 1.1	53 - 97
Women	0.5 - 0.9	44 - 80
Urine	1 - 1.5 g / 24 hrs.	(8.84 – 13.3) mmol/24 hrs.

Normal values for creatinine clearance

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

Each laboratory should check if references ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. **Mod. acc. To Bartels,H. et.al.(1971). Clin. Chem.**
2. **Schimeister.J.et.al.(1964).Dtsch.Med.Wschr.89:1018**
3. **Sarre, H. (1959) Nierenkrankheiten. Georg ThiemeVerlag, Stuttgart**
4. **Schirmeiste.J.et.al.(1964).Dtsch.Med.Wschr.89:1640**

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