Creatinine PAP

Creatinine PAP Reagent Test Kit

Intended Use

Reagent for the quantitative determination of Creatinine in serum, plasma or urine.

Order Information

Item Code.	Pack Size	
750119934841	R1: 2 x 45 mL;	R2 : 2x 15 mL;
750129934840	R1: 2 x 20 mL;	R2 : 2 x 10 mL

Summary

Creatinine is the final metabolite of creatine produced in muscle cells. Serum creatinine concentration depends on the production of creatinine in muscle cells and the excretion of creatinine in urine. In kidney disease and muscle disease with low renal function, the serum creatinine concentration increases. In muscular dystrophy, the concentration of serum creatinine decreases, and the excretion of creatinine in urine is proportional to the total muscle mass, and is not affected by food, urine output, and renal tubular reabsorption, so it can be used for the examination of glomerular filtration function. In the past, the Jaffe method was used to measure creatinine, and recently, the enzymatic method with less non-specific reaction is widely used to measure creatinine.

Principle

The creatinine in the sample generates creatine under the action of creatinase. Then, hydrogen peroxide is generated under the action of creatinase and sarcosine oxidase, and hydrogen peroxide generates quinone pigment under the action of peroxidase to determine the concentration of creatinine.

Creatininase

Creatinine + H_2O ----------> Creatine

Creatinase

Creatine + H_2O ----------> Sarcosine + Urea

Sarcosine oxidase

Sarcosine + H_2O + O_2 ----------> Glycine + Formaldehyde + H_2O_2

Peroxidase

4-AA+TODB + H_20_2+ H_3^+0 ----------> Fuchsia quinone pigment + 5 H_2O

Storage Instruction and Reagent Stability

Reagents are stable until their expiration date when stored at 2 - 8°C.

Reagent Preparation

Reagents are ready-to-use for both manual method and automated chemistry analyzers.

Reagent Composition

Contents	Concentration
Reagent 1 (R1)	
GOOD'S buffer	50 mmol/L
Creatinase	>20 U/mL
Sarcosine oxidase	>5 U/mL
TODB	>0.5 mmol/L
Reagent 2 (R2)	
GOOD'S buffer	50 mmol/L
Peroxidase	>1 U/mL
Creatininase	>100 U/mL
4-AAP	>0.5 mmol/L

Sample Material

Fresh serum or plasma (heparin or EDTA).
Fresh urine, urine specimens are diluted 1:10 with normal saline (or distilled water, deionized water).
Serum samples can be stored at 15°C - 25°C for 7 days, (-15) - (-25) °C for 3 months.

Traceability

The assigned value of the calibrator has been traceable to the reference method reference materials NIST SRM 967.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength (Main / Sub)	546 nm / 700 nm
Optical path	1cm
Temperature	37^{0}C

Measurement

	Blank	Sample/Calibrator
Sample/Calibrator	-	4 µL
Dist. Water	4 µL	-
Reagent 1	210 µL	210 µL
Mix, incubate 5 min. & read absorbance A1.		
Reagent 2	70 µL	70 µL
Mix & read absorbance A2, after 5 min.		

Conversion Factor

mg/dL *88.4 =µmol/L = 10^6 pmol/L

Calibrators and Controls

It is recommended to use TruCal U calibrator.

1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2. For internal quality control DiaSys TruLab N, P and TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Reference Range

Serum/plasma (adults)	
Men:	0.67 - 1.17 mg/dL
Women:	0.51 - 0.95 mg/dL
1st morning urine (adults)	
Men:	40 - 278 mg/dL
Women:	29 - 226 mg/dL
24-hour urine (adults)	
Men:	980 - 2200 mg/24h
Women:	720 – 1510 mg/24h
Creatinine clearance	66 - 143 ml/min

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

Performance Characteristics Measuring Range

The test has been developed to determine creatinine concentrations within a measuring range from 0.17-135 mg/dL. The upper limit of the measuring range at the same time depends on the photometer linearity of the analyzer and may vary. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 d/L) and the result multiplied by 2.

Sensitivity/Limit of Detection

The lower limit of detection is 0.17mg/dL.

Precision

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 1 day, and each batch was measured for 5 times. The results are as follows:

a) Precision (N = 20)

	Mean (mg/dL)	CV(%)
Level 1	1.32	2.34
Level 2	5.10	0.54

b) Intraday precision (N = 5)

	Mean (mg/dL)	CV(%)
Level 1	1.25	0.71
Level 2	4.87	0.89

Method Comparison
A comparison of Creatinine PAP FS (y) with a commercially available test (x) using 102 serum and plasma samples within a range of 0.4 - 18 mg/dL gave following results: y = 1.02 x – 0.02 mg/dL; r = 1.00.
A comparison of Creatinine PAP FS (y) with a commercially available test (x) using 29 urine samples within a range of 1.4 – 27 mg/dL gave following results: y = 1.051 x – 0.08 mg/dL; r = 1.00.

Specificity/Interferences
No interference was observed by ascorbic acid up to 50 mg/dL, Direct Bilirubin up to 30 mg/dL, hemoglobin up to 400 mg/dL, Creatine up to 40 mg/dL and lipemia up to 1500 mg/dL triglycerides. Proline in concentrations > 12 mg/dL leads to falsely elevated values. For further information on interfering substances refer to Young DS [8].

Warning and Precautions
1. Because test specimens may be contaminated with HBV or HIV, to prevent infection, wear gloves when handling.
2. Reagent contains preservative. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Preservative reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Unsealed reagents should be stored in a sealed container according to the specified method.
5. Reagents with different lot numbers should not be interchanged or mixed.
6. Avoid using diluted reagents, otherwise correct results will not be obtained.
7. It is forbidden to use any precipitate found in the reagent.
8. The container and accessories of this kit must not be used for other purposes.
9. Dispose of test tubes and other equipment that have come into contact with the test specimen in accordance with the relevant medical waste disposal regulations. You have the following options: autoclave for 15 minutes at 121°C in a pressure sterilizer (however, wastes containing hypochlorous acid solution should not be treated with a pressure sterilizer), or immerse in hypochlorous acid solution (effective concentration greater than 1000ppm) for one hour the above.

Limitations
Do not use haemolysed samples.

Literature

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Notes on Symbols and Marks

	Consult instructions for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	*In vitro diagnostic* medical device
	Temperature limit
	Do not re-use
CONT.	The pack contains
	Recycle
	Date of manufacturer

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

DiaSys Diagnostics India Private Limited
Plot No. A – 821, T.T.C. Industrial Area, MIDC,
Mahape, Navi Mumbai – 400710.
Maharashtra, India.

Customer Care
For feedback/queries contact customer care at :
Toll Free number : 1800 120 1447
Email ID : helpdesk.service@diasys.in
Website : www.diasys.in

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