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CREATININE

REF 033K

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

Quantitative determination of creatinine in serum or heparinized plasma or urine by a colorimetric kinetic method.

DIAGNOSTIC SIGNIFICANCE

Creatinine, an anhydride of creatine, is a waste product excerted by the kidneys[1]. Most of the creatine is found in muscle tissues where it is present as creatine phosphate and serves as a high energy storage reservoir for conversion to ATP. Independent of diet, serum creatinine concentrations depend almost entirely upon its excretion rate by the kidneys. For this reason its elevation is highly specific for kidney diseases[2].

RANGE OF EXPECTED VALUES[3]

1. CREATININE

Serum	Male	0.6-1.2 mg/dL (53-106 µmol/L)
	Female	0.5-1.0 mg/dL (44-88 µmol/L)
Urine 24 h.	Male	1.0-2.0 g/day
	Female	0.8-1.8 g/day

2. CREATININE CLEARANCE (ENDOGENOUS)

Male	97-137 ml/minute
Female	88-128 ml/minute

METHOD PRINCIPLE

The assay of creatinine has been based on the reaction of creatinine with alkaline picrate as described by Jaffe.

Creatinine +Picric Acid $\xrightarrow{\text{Alkali}}$ Creatinine - Picrate complex (yellow- orange)

Creatinine reacts with picric acid in alkaline conditions to form a color complex that absorbs light which is measured at 505 nm. The rate of formation of color is proportional to the creatinine concentration in the sample.

REAGENTS

1. **CREATININE BUFFER:**
   A solution containing 250 mM Sodium hydroxide.
2. **PICRIC ACID REAGENT:**
   A solution containing 14 mM Picric acid.
3. **CREATININE STANDARD (1.5mg/dL) or 132.6 µmol/L:**
   A solution containing Creatinine in Hydrochloric acid with preservative.

STORAGE & STABILITY

Store all reagents at room temperature. All reagents are stable upto expiration date indicated on the individual bottle label. Combined working reagent is stable upto 7 days at room temperature when stored in dark.

PRECAUTIONS

1. This reagent is for "*in vitro*" diagnostic use only.
2. Creatinine buffer is an alkali. Avoid contact with skin.

Creatinine Picric Acid Reagent is a strong Oxidizing agent. Avoid contact with skin. WIPE ANY SPILLAGE, SINCE PICRIC ACID IS EXPLOSIVE.

REAGENT DETERIORATION

The reagent should be discarded if:

1. Turbidity has occurred. Turbidity may be a sign of contamination.
2. The reagent fails to meet linearity claims or fails to recover control values in the stated range.

MATERIALS PROVIDED

Creatinine Buffer, Picric Acid Reagent & Creatinine Standard (1.5mg/dL).

MATERIALS REQUIRED BUT NOT PROVIDED

Pipetting Devices, Timer, Heating Bath/Rack, Test Tube/Rack, Vessel for combining reagents (Glass or Plastic) Spectrophotometer with a temperature controlled cuvette.

SPECIMEN

1. Serum, heparinized plasma or urine (dilute 50 times) i.e. 1 ml urine + 49 ml water.
2. Creatinine in serum is stable for twenty four hours at refrigerated temperatures (2-8 °C) and for several months when frozen (-20 °C) and protected from evaporation and contamination.
3. 24 hours urine specimens must be preserved with 15 grams of boric acid .

WORKING REAGENT PREPARATION

Combine equal volumes of creatinine buffer and picric acid reagent, mix well. Stable upto 7 days at room temperature when stored in dark.

PROCEDURE PARAMETERS

Wave length .....505 nm (490-510 nm)
Reaction Type .....Kinetic-fixed time with standard
Measurement Time.A1= after 20 seconds. A2 = 60 seconds after A1
Reaction Direction ..... Increasing
Reaction Temperature ..... 25 °C, 30 °C or 37 °C
Linearity.....18 mg/dL
Sample Volume .....100 µl (Semimicro) 250 µl (Macro)
Working Reagent volume ....1 ml (Semimicro) 2.5 ml (Macro)
Standard concentration .....1.5 mg/dL (132.6 µmol/L)

PROCEDURE (AUTOMATED)

Refer to the specific instrument application manual available from us.

PROCEDURE (MANUAL)

Pipette into clean cuvettes or tubes

	SEMIMICRO		MACRO	
	STD	TEST	STD	TEST
Working Reagent	1.0 ml	1.0 ml	2.5 ml	2.5 ml
Prewarm at 25 °C, 30 °C or 37 °C for 2 minutes and add:				
Standard	0.1ml	-	0.25ml	-
Sample (Serum/Plasma/ 50 times diluted urine)	-	0.1ml	-	0.25 ml
After exactly 20 seconds read and record absorbance A1 against distilled water at 505 nm. At exactly 60 seconds after the A1, read and record the absorbance A2 and determine ΔA.				

NOTE: Temperature must be kept constant during the test.

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CALCULATION OF RESULTS

1. SERUM/PLASMA

$$\frac{\Delta A \text{ (Sample)}}{\Delta A \text{ (Standard)}} \times \text{Conc. of Standard 1.5mg/dL)} = \text{creatinine in sample mg/dL}$$

2. URINE

$$\frac{\Delta A \text{ (Sample)}}{\Delta A \text{ (Standard)}} \times \text{Conc. of Standard 1.5mg/dL} \times 50 \text{ (dilution factor)} = \text{creatinine in sample mg/dL}$$

Creatinine concentration in 24 h urine :

$$\frac{\text{mg/dL}}{100} \times \text{ml Urine/24 h} = \text{mg creatinine/24 h}$$

or

$$\frac{\mu\text{mol/L}}{1000} \times \text{ml Urine/24 h} = \mu\text{mol creatinine/24 h}$$

3. CREATININE CLEARANCE

$$\frac{\text{Urine creatinine mg/dL} \times \text{ml urine/24 h}}{\text{serum creatinine mg/dL} \times 24 \times 60} = \text{ml/minute}$$

EXAMPLE

Standard	A1	=	0.098
	A2	=	0.133
	ΔA	=	0.035
1. Sample (Serum/Plasma)	A1	=	0.299
	A2	=	0.327
	ΔA	=	0.028

Creatinine in urine = $\frac{0.028}{0.035} \times 1.5 = 1.2$ mg/dL

2. Urine Sample (50 times diluted)

A1	=	0.141
A2	=	0.181
ΔA	=	0.040

Creatinine in urine = $\frac{0.040}{0.035} \times 1.5 \times 50 = 85.7$ mg/dL

Assume that patient's 24 hrs. urine output was 2500 ml. Then his creatinine concentration in 24 hrs. urine would be:

$\frac{85.7}{100} \times 2500 = 2142$ mg/24 hrs. or 2.1 g/24 hrs.

Creatinine Clearance

$$\frac{85.7 \times 2500}{1.2 \times 24 \times 60} = 124 \text{ ml/min.}$$

PERFORMANCE CHARACTERISTICS

Linearity : 18 mg/dL

COMPARISON : UDI reagents (y) was compared with similar UDI reagent for other systems(x) which in turn is matching with CAPS survery results. The systematic difference between the results were within CLIA specified limits, N=25

Correlation Cofficient 0.99

Regression Equation y=0.84x + 0.28

PRECISION:

	Mean (mg/dL)	S.D.	C.V.%
Within run	1.7	0.05	2.72
Run to run	5.7	0.14	2.53

PROCEDURE LIMITATIONS

Albumin at a concentration of 10.0 g/dL contributes 0.2 mg/dL to the creatinine value, moderate hemolysis (0.2 g/dL Hgb), grossly icteric and lipemic samples will give elevated results. Acetoacetate above 10 mg/dl will interfere with the results. Refer "4" for interfering substances.

QUALITY CONTROL

For accuracy and precision check, we recommend the use of normal and abnormal UDI controls based on human serum.

ORDERING INFORMATION:

UDITROL 'N' (Normal Serum Control) REF # 070N-010 2x5 ml
UDITROL 'A'(Abnormal Serum Control) REF # 070A-010 2x5 ml

REFERENCES

1.Henry, J.B., Clinical Diagnosis and Management by Laboratory Method, 16th ed. Saunders, Philadelphia PA, p. 263, (1974).
2.Vasilades, J. Clin. Chem. 22:1664 (1976).
3.Tietz, N.W., Foundamentals of Clinical Chemistry, W.B. Saunders, R.S. Phila, p 1211 (1976).
4.Young, D.S. et al., Clin.. Chem. 21 (1975).

PRODUCT AVAILABILITY

CREATININE JAFFE'S METHOD

REF # 033K-480	**2 x 120 ml**
REF # 033K-240	**1 x 120 ml**

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CE