QUANTON BIOLIFE SCIENCES

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Creatinine (Alkaline Picrate)Test Kit
(Alkaline Picrate Method)

QBL/PDS/CRA_034

Quantitative determination of Creatinine in serum / plasma / Urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
CRA 100	2 X 50 mL
CRA 200	2 X 100 mL
CRA 1000	2 X 500 mL

CLINICAL SIGNIFICANCE

Creatinine is the catabolic product of high energy storage compound, Creatinine Phosphate formed in muscle. The amount of creatinine produced is fairly constant and is primarily a function of muscle mass. Creatinine is excreted out of body entirely by the kidneys.
Elevated levels are found in renal dysfunction, reduced renal blood flow (shock, dehydration, congestive heart failure) diabetes acromegaly. Decreased levels are found in muscular dystrophy

Method

Fixed time test without deproteinization according to the Jaffé method

PRINCIPLE

Creatinine reacts with alkaline picrate to produce orange coloured complex. Intensity of the colour formed during the fixed time is directly proportional to the amount of creatinine present in the sample.

REAGENT

Reagent I : NaOH Reagent
Reagent ll : Picrate reagent
Creatinine Standard : 2 mg/dl (0.16 mmol/L)

REAGENT PREPARATION

Mix equal volumes of the two reagents prior to use. A measuring cylinder may be used for this as the exact volumes are not critical, eg: to 5 mL of Picric Acid reagent add 5 mL of NaoH reagent.

REAGENT STORAGE AND STABILITY

Prior to use:
When stored at 15-30°C and protected from direct sunlight, the reagents are stable until the expiry date stated on the bottle and kit box labels.
Working Reagent:
The working reagent is stable for 3 days when stored capped at 2-8°C

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma, Urine
Stability:
in serum /plasma: 7 days at 4 – 8°C
at least 3 months at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!
in urine: 1 day at 20 – 25°C
6 days at 4 – 8°C
6 months at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!
Dilute urine 1 + 19 with dist. water; multiply the result by 20.

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	500 nm
Measurement	Against D/W blank
Cuvette	1 cm light path
Reaction Temperature	Room Temperature
Reaction Type	Fixed Time
Reaction Direction	Increasing
Sample Volume	100 µl
Reagent Volume	1000 µl
Delay/Lag/Time	30 sec.
Interval Time	60 sec.
No. of Readings	01
Low Normal at 37°C	0.8 mg/dl
High Normal at 37°C	1.4 mg/dl
Linearity at 37°C	25 mg/dl

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	100 µl
Standard	-	100 µl	-
Working Reagent	1000 µl	1000 µl	1000 µl

- Mix and after 30 secs at R.T., read initial absorbance and start timer simultaneously. Read again after 1 min. determines ΔAbs/min. of standard (As) and sample (Ac) against reagent blank.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 25 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

Creatinine mg /dl Serum	ΔA / Δ As x C
Creatinine mg /dl Urine	ΔA / Δ As x C x 20
Urine Creatinine g/24 Hrs	Urine Creatinine in g/L x Vol. of urine in 24 Hrs.

C = Concentration Standard

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Creatinine standard** have been made traceable to the NIST (National Institute for Standardization) Standard Reference Material SRM 967 using level 1 and 2 and therefore to GC-IDMS (gas chromatography - isotope dilution mass spectrometry).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	0.987	0.025	2.53%
Path	3.420	0.115	3.36%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	0.988	0.021	2.10%
Path	3.441	0.094	2.73%

LINEARITY

The method is linear upto a concentration of 25mg/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Creatinine is 0.2 mg/dL.

METHOD COMPARISON

A comparison of Paramcare Creatinine with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

	MEN	WOMEN
SERUM	0.8 - 1.4	0.7 - 1.2 mg/dl
24h URINE	1.0 - 2.0	0.8 - 1.8 G/24h

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Hemoglobin: No interference found upto 500 mg/dL.
- Lipemia: No interference found upto 1250 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Henry, J.B, Young D.S. teitz N.W, Vasilades, J, Can. Chem (1972), 18.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13,
Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi,
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