CREATININE

Colorimetric determination of Creatinine in biological liquids without deproteinization

TEST SUMMARY
Creatinine forms with Picric acid an orange compound which intensity is spectrophotometrically measured at 510 nm.

SAMPLES
Serum.
Diluted urine 1:25 with distilled water.
Stability 24 hours at 4°C.

REAGENTS
Reagent A:	Sodium Idrosside 0.3 M.
Reagent B:	Picric Acid 18 mM
Standard:	Creatinine 2 mg/dl; stabilizers and preservatives.

MATERIAL REQUIRED BUT NOT SUPPLIED
Normal laboratory equipment. Spectrophotometer UV/VIS with thermostatation. Automatic Micropipette. Cuvette in optical glass or monouse in optical polystyrene. Physiologic solution.

PRECAUTIONS
Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

REAGENTS PREPARATION
Mix some Reagent A with some Reagent B.
Reagents are stored at 15-25°C and are stable until expiration date on label.
Work Reagent is stable 7 days at 4-30°C.

PROCEDURE
Kind of analysis:	Fixed Time
Reading time:	30-60 seconds
Wavelength:	510 nm (490-530)
Delay:	30 seconds
Temperature:	25°C, 30°C, 37°C
Zero:	Reagent blank

Reagents	Blank	Standard	Sample
Distilled water	100 µl	--	--
Standard	--	100 µl	--
Sample	--	--	100 µl
Work Reagent	1000 µl	1000 µl	1000 µl

CALCULATION
SERUM Creatinine (mg/dl)

(A sample / A standard) x 2

SERUM Creatinine (µM)

(A sample / A standard) x 176,8

URINE Creatinine (g/24h)

$$\frac{\text{(A sample / A standard) x 2 x 25 x l di urina}}{1000}$$

EXPECTED VALUES
Serum

Men	0.6 – 1.6 mg/dl	(53 – 142 µM)
Women	0.6 – 1.3 mg/dl	(53 – 115 µM)

Urine

0.8 – 1.5 g/24h

Every laboratory should establish own reference intervals in accordance with own population.

NOTES
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/ QUALITY CONTROL
It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH **10 x 5 ml**
Control Sera normal values

QP 0050 CH **10 x 5 ml**
Control Sera pathological values

TEST PERFORMANCE
Precision

Intra-assay (n = 20)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	0.8	0.0324	4.06
Sample 2	1.6	0.0324	2.03

Inter-assay (n = 20)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	0.805	0.0394	4.89
Sample 2	1.595	0.0394	2.47

Linearity
The method is linear up to 10 mg/dl (885 µM).

Methods comparison
A comparison with a commercial available product gave the following results in a comparison on 50 samples:

Creatinine LTA = x
Creatinine competitor = y
n = 50

y = 0,99195x + 0,001693 r = 0,98822

WASTE DISPOSAL
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING
CODE CC01400	**(600 TESTS)**	
Reagent A	3 x 100 ml	(liquid)
Reagent B	3 x 100 ml	(liquid)
Standard	1 x 5 ml	(liquid)

REFERENCES

Bartels H. e coll.-Clin. Chem. Acta 37;193 (1972).
Henry J.B., - Clin. Diagnosis and Management - 17th edition – Saunders publisher – 1984.
Cook J. C. H. – Clin. Chem Acta 32, 485 (1971).

MANUFACTURER

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SYMBOLS
IVD	Only for IVD use
LOT	Lot of manufacturing
REF	Code number
	Storage temperature interval
	Expiration date (year, month)
	Warning, read enclosed documents
	Read the directions
	Biological risk

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