

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 Iodosside 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 thermostatisation. 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 4-30°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)

$$(A \text{ sample} / A \text{ standard}) \times 2$$

SERUM Creatinine (µM)

$$(A \text{ sample} / A \text{ standard}) \times 176,8$$

URINE Creatinine (g/24h)

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

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

$$y = 0,99195x + 0,001693 \quad r = 0,98822$$

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)









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SYMBOLS

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

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