BIOLABO
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CREATININE Enzymatic method

Reagent for quantitative determination of creatinine in human serum and plasma or urines.

REF 90107 **R1** 1 x 120 mL **R2** 1 x 40 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision : www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows the quantification of creatinine in human serum and plasma or urines to screen its level.

GENERALITIES (1)

Creatinine is a product of degradation of creatine necessary for the production of energy by muscles. It's excreted principally by glomerular filtration in kidney and eliminated by urines. It's concentration in healthy subjects is almost constant. Thus, elevated level of creatinine in blood may indicate renal insufficiency (reduction of its excretion)

PRINCIPLE

In the first reaction, creatinase and sarcosine oxidase were used in the enzymatic hydrolysis of endogenous creatine to produce hydrogen peroxide, that is eliminated by catalase.
In the second reaction, the catalyze is inhibited by sodium azide, and creatinase and 4-aminoantipyrin (4-AA) were added, and only the creatine generated from creatinine by creatininase was hydrolyzed sequentially by creatinase and sarcosine oxidase to produce hydrogen peroxide.
This newly formed hydrogen peroxide was measured in a coupled reaction catalyzed by peroxides, with N-ethyl-n-sulphopropyl-m toluidine (TOPS)/4-AA as a chromogen.

REAGENTS COMPOSITION

R1	**CRZ**	Creatinine Reagent 1
MOPS		25 mmol/L
TOPS		0,5 mmol/L
Creatinase		10 UK/L
Sarcosine Oxidase		5 KU/L
Catalase		3 KU/L
EDTA		1 mmol/L
pH 7.5		
R2	**CRZ**	Creatinine Reagent 2
MOPS		90 mmol/L
Creatinase		30 KU/L
Peroxidase		10 KU/L
Sodium Azide		0,5 g/L
pH 7.5		

EUH210: Safety Data Sheet (MSDS) available on request

According to 1272/2008/EC regulation, these reagents are not classified as dangerous

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when used and stored as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- Separate reagents are stable at least 8 weeks.
- Discard reagent if cloudy or if reagent blank is > 0.100 at 545 nm.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or heparinized plasma.

Urines: Collect during precisely timed intervals (4, 12 or 24 h). Dilute 1+50 in demineralized water before determination.

Creatinine is stable for 24 h at 2-8°C.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

I REFERENCE INTERVALS (2)

Serum or plasma	[µmol/L]	mg/dL
0 – 1 year	[4 – 29]	0.04 - 0.33
2 – 5 years	[4 – 40]	0.04 - 0.45
6 - 9 years	[18 – 46]	0.20 - 0.52
10 years	[19 – 52]	0.22 - 0.59
Adult (Male)	[55 - 96]	0.62 - 1.10
Adult (Female)	[40 - 66]	0.45 - 0.75

Urines (Jaffe)	[µmol/kg/24 h]	mg/kg/24h
Infant	[71-177]	8 - 20
Child	[71-194]	8 - 22
Adolescent	[71-265]	8 - 30
Adult (Male)	[124-230]	14 - 26
Adult (Female)	[97-177]	11 - 20

In urines, declines from fifth decade to achieve 10mg/kg/day at age 90 years.

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On KENZA 240TX, 37°C, 545 nm

Linearity range: between 54 and 8850 µmol/L (0.61 and 100 mg/dL)

Detection limit: 12 µmol/L (0.14 mg/dL)

Precision:

Within-run N = 20	*Level 1*	*Level 2*	*Level 3*
Mean (µmol/L)	43	127	677
S.D. µmol/L	1.74	3.08	5.14
C.V. %	4.0	2.4	0.8

Between run N = 20	*Level 1*	*Level 2*	*Level 3*
Mean (µmol/L)	44	124	668
S.D. µmol/L	1.73	3.52	13.58
C.V. %	4.0	2.8	2.0

Analytical sensitivity: approx. 0,023 abs for 1 mg/dL (88,5 µmol/L)

Interferences studies on Kenza 240TX:

Turbidity	Negative interference from 0,090 abs
Ascorbic acid	No interference up to 2500 mg/dL
Total bilirubin	No interference up to 502 µmol/L
Direct bilirubin	No interference up to 500 µmol/L
Hemoglobin	Negative interference from 109 µmol/L
Glucose	No interference up to 1098 mg/dL

Other substances may interfere (see § Limits)

Comparison with commercially available reagent on automatic analyzer:

- Serums (n=59) from 26 to 226 µmol/L (0.3 mg/dL to 2.56 mg/dL):

  y = 0.9864 x + 0.0097 r = 0.9990

- Urines (n=59) from 1377 to 12258 µmol/L (15.6 mg/dL to 139 mg/dL):

  y = 1.0171 x – 0.1057 r = 0.9999

Calibration stability:

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

CALIBRATION

- REF 95015 Multicalibrator traceable to SRM914 and validated according to ANSM recommendations (Use of 1 zero point, 1medium level and 1 high level to calibrate).

The calibration frequency depends on proper instrument functions and on the preservation of reagent

QUALITY CONTROL

- REF 95010 EXATROL-N Level 1
- REF 95011 EXATROL-P Level 2
- REF 95012 Urinary Controls
- ANSM recommends low, medium and high controls
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Manual method

Let stand reagent and specimens at room temperature.

Reagent 1	450 µL
Specimen (*)	10 µL
Mix. Let stands for 5 minutes at 37°C.Read absorbance A1 at 545nm (525-565) against reagent blank. Add:	
Reagent 2	150 µL
Mix. Let stands for 5 minutes at 37°C.Read absorbance A2 at 545nm (525-565) against reagent blank.	

(*) Demineralized water, calibrator(s), controls or specimen as follows: serum, plasma, or urines (diluted 1+49 in demineralised water).

1. Performances with manual procedure should be validated by user.
2. Applications for KENZA Analyzers and others are available on request.

CALCULATION (1)

Serum, plasma

With calibrator REF 95015:

Calculate ∆Abs. = (A2 – 0,75 A1) for Assay and Calibrator.

Replace in the formula as follows:

$$\text{Concentration} = \frac{\Delta\text{Assay}}{\Delta\text{Calibrator}} \times \text{Calibrator concentration}$$

Urines (g/24h)

Multiply result by 50 (dilution factor) and V (Urines volume in liter/24h)

Urines (mg/Kg/24h)

$$\text{mg/Kg/24h} = \frac{\text{Creatinine Urines (g/24h) x 1000 mg / g*}}{\text{Patient's weight (Kg)}}$$

* Result conversion from gram to milligram

REFERENCES

(1) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1241-1245.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 316-321*

(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-190 to 3-211*

(4) *SRM : Standard Reference Material ®*