



BIOLABO
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CREATININE Enzymatic method

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

REF K1117	R1 2 x 15 mL	R2 1 x 10 mL
REF K2117	R1 1 x 30 mL	R2 1 x 10 mL
REF K4117	R1 2 x 30 mL	R2 1 x 20 mL



Made In France

TECHNICAL SUPPORT AND ORDERS

Tel: (33) 03 23 25 15 50

support@biolabo.fr

Latest revision : www.biolabo.fr

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (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 peroxidase, with N-ethyl-n-sulphopropyl-m toluidine (TOPS)/4-AA as a chromogen.

REAGENTS COMPOSITION

R1	CRZ	Buffer Enzymes 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	Buffer Enzymes 2
MOPS		90 mmol/L
Creatinase		30 KU/L
Peroxidase		10 KU/L
Sodium Azide		0,5 g/L
pH 7.5		

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 capped 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:

- Reagents R1 and R2 are stable at least 8 weeks.
- Discard reagent if cloudy or if its abs. 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. Biochemistry Clinical Analyzer KENZA One, KENZA 240TX/ISE or KENZA 450TX/ISE

I REFERENCE INTERVALS (2)

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

Urines (Jaffe)	[$\mu\text{mol/kg/24 h}$]	mg/kg/24h
Infant	[71-177]	8 to 20
Child	[71-194]	8 to 22
Adolescent	[71-265]	8 to 30
Male	[124-230]	14 to 26
Female	[97-177]	11 to 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 $\mu\text{mol/L}$ (0.61 and 100 mg/dL)

Detection limit 12 $\mu\text{mol/L}$ (0.14 mg/dL)

Precision:

Within-run N = 20	Level 1	Level 2	Level 3	Between run N = 20	Level 1	Level 2	Level 3
Mean ($\mu\text{mol/L}$)	43	127	677	Mean ($\mu\text{mol/L}$)	44	124	668
S.D. $\mu\text{mol/L}$	1.74	3.08	5.14	S.D. $\mu\text{mol/L}$	1.73	3.52	13.58
C.V. %	4.0	2.4	0.8	C.V. %	4.0	2.8	2.0

Analytical sensitivity: approx. 0,023 abs for 1 mg/dL (88,5 $\mu\text{mol/L}$)

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 $\mu\text{mol/L}$
Direct bilirubin	No interference up to 500 $\mu\text{mol/L}$
Hemoglobin	Negative interference from 109 $\mu\text{mol/L}$
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 $\mu\text{mol/L}$ (0.3 mg/dL to 2.56 mg/dL):

$$y = 0.9864 x + 0.0097 \quad r = 0.9990$$

- Urines (n=59) from 1377 to 12258 $\mu\text{mol/L}$ (15.6 mg/dL to 139 mg/dL):

$$y = 1.0171 x - 0.1057 \quad r = 0.9999$$

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

Performances and stability data on KENZA 450TX/ISE and KENZA One are available on request

CALIBRATION

- REF 95015 Multicalibrator traceable to SRM914
ANSM recommendations :Use 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
- 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:

- Prepare a fresh control serum and repeat the test
 - If control is still out of range, use a new vial of fresh calibrator
 - 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.

I PROCEDURE

Let stand reagents and specimens at room temperature













- Depending on specimen used, refer to specific applications of KENZA Analyzer.
- Contact support@biolabo.fr for more details

CALCULATION

The analyzer provides directly final result.
Refer to the User's manual of KENZA analyzer.

REFERENCES

- TIETZ N.W. *Textbook of clinical chemistry*, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1241-1245.
- Clinical Guide to Laboratory Test*, 4th Ed., N.W. TIETZ (2006) p. 316-321.
- YOUNG D.S., *Effect of Drugs on Clinical laboratory Tests*, 4th Ed. (1995) p.3-190 à 3-211
- SRM : Standard Reference Material ®

 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