BIOLABO
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CREATININE Kinetic method

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

REF K1107	**R1** 2 x 15 mL	**R2** 2 x 15 mL	**R3** 1 x 10 mL
REF K2107	**R1** 2 x 25 mL	**R2** 2 x 25 mL	**R3** 1 x 10 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 (automated method).
It allows the quantification of creatinine in human serum and plasma or urines to screen its level.

GENERALITIES (1)

Interconversion of phosphocreatine and creatine is a particular feature of the metabolism processes of muscle contraction. Creatine and phosphocreatine partially convert to a waste product, creatinine. Thus, the amount of creatinine produced each day is related to the muscle mass (and body weight), age, sex, diet or exercise and does not greatly vary from day to day.

PRINCIPLE (4)(5)

Colorimetric reaction (Jaffe reaction) of creatinine with alkaline picrate measured kinetically at 490 nm (490-510), without any pre-treatment step. This reaction has been improved (specificity, speed and adaptability) by the development of an initial-rate method.

REAGENTS COMPOSITION

R1 CRE Reagent 1

Disodium Phosphate	6.4	mmol/L
Sodium hydroxide	150	mmol/L

Attention
Met Corr.1: H290 - May be corrosive to metals
Skin Irrit.2 : H315 - Causes skin irritation
Eye Irrit.2: H319 - Causes serious eye irritation
Classification due to: Sodium Hydroxide 1- < 2.5%
P264: Wash hands thoroughly after handling,
P280: Wear protective gloves/protective clothing/eye protection/face protection,
P302+P352: IF ON SKIN: Wash with soap and water,
P305+P351+P338: IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing,
P337+P313: If eye irritation persists, get medical advice/attention,
P390: Absorb spillage to prevent material damage.

R2 CRE Reagent 2

Sodium dodecyl sulphate	0.75	mmol/L
Picric acid	4.0	mmol/L

pH 4.0

According to 1272/2008 regulation, this reagent is not classified as dangerous

R3 CRE Standard

Refer to the batch specific values (urines) indicated in the label of the vial and in the certificate of analysis.

EUH210: Safety Data Sheet (MSDS) available on request

According to 1272/2008 regulation, reagent R3 is 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 18-25°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 1 year.
- Discard reagent if cloudy or if its abs. is > 0.300 at 490 nm.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or heparinized plasma.

Urines: Collect during precisely timed intervals (4, 12 or 24 h).
Dilute 1+19 in demineralized water before determination.

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

LIMITS (1) (2) (3) (5)

Some antibiotics interfere also with the determination of creatinine according to Jaffe method.

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

REFERENCE INTERVALS (2)

Serum or plasma	[µmol / L]	mg/dL
Male	[80-115]	0.9 to 1.3
Female	[53-97]	0.6 to 1.1

Urines	[µmol / kg / 24 h]	mg / kg / 24 h
Male	[124-230]	14 to 26
Female	[97-177]	11 to 20

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

I PERFORMANCES

KENZA 240TX, 37°C, 505 nm on serum
(Bi-reagents, calibration 2 points):

Detection limit: 4.2 µmol/L (0.05 mg/dL)

Quantification limit: 35 µmol/L(0.40 mg/dL)

Linearity Range:
Between 35 µmol/L(0.40 mg/dL) and 1328 µmol/L (15 mg/dL)

Precision:

Within-run N = 20	*Level 1*	*Level 2*	*Level 3*
Mean (µmol/L)	58.2	141.3	509.1
S.D. µmol/L	1.07	1.82	8.14
C.V. %	1.8	1.3	1.6

Between run N = 20	*Level 1*	*Level 2*	*Level 3*
Mean (µmol/L)	58.2	145.1	514.1
S.D. µmol/L	2.34	5.14	11.79
C.V. %	4.0	3.5	2.3

Comparison studies with commercially available reagent:
Realised on human serum (n=123) between 0.41 and 13.6 mg/dL
y = 1.1925x - 0.113 r = 0.9879

Interferences:

Turbidity	Negative interference from 0.223 OD
Total bilirubin	Negative interference from 209 µmol/L
Direct bilirubin	Negative interference from 24 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 966 mg/dL
Hemoglobin	Negative interference from 133 µmol/L

Other substances may interfere (see § Limits)

On-board stability: 2 separate reagents are stable 7 days

Calibration Frequency: 4 days

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 (6)

• REF 95015 Multicalibrator for quantitative determination in serum/plasma: value traceable to SRM967.
• Standard (vial R3) for quantitative determination in urines: value traceable to SRM914.

According to ANSM: 1 zero-point, 1 intermediate level and 1 high level have been used to determine these values.

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

QUALITY CONTROL

• REF 95010 EXATROL-N Level 1
• REF 95011 EXATROL-P Level 2
• REF 95012 Urinary Controls (to be diluted as sample before test)
• 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

• Serum/plasma:
- Refer to the dedicated application of the KENZA Analyzer used

• Urines:
- Use Standard (vial R3) for calibration (do not dilute)
- Predilute controls REF 95012 and specimens (1+19) in demineralized water before test.

CALCULATION

• Serum/plasma:
The analyzer provides directly final result.
Refer to the instruction of use of KENZA analyzer.

• Urines with manual predilution (1+19):
Multiply the analyser results by dilution factor 20.

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) Fabiny D. L., et Ertingshausen G., Clin. Chem. (1971), 17, p.696-700.
(5) D. Labbé et al., Ann. Biol. Clin. (1996), 54, p. 285 – 298
(6) 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