BIOLABO
www.biolabo.fr

MANUFACTURER:
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CK-NAC IFCC

Reagent for quantitative determination of Creatine Kinase activity [EC 2.7.3.2] in human serum.

I REF K1207	**R1** 2 x 16 mL	**R2** 1 x 8 mL
I REF K2207	**R1** 2 x 32 mL	**R2** 2 x 8 mL
I REF K4207	**R1** 2 x 40 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
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support@biolabo.fr
Latest revision : www.biololabo.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 global activity of the creatine kinase enzyme in human serum.

GENERALITIES (1)

Creatine kinase (CK) is found mainly in cardiac, cerebral and skeletal muscle tissues. So, any damage or disease of these tissues (myocardial infarction, acute cerebrovascular disease, muscular dystrophy) will result in an increased level of CK activity in serum.

PRINCIPLE (4) (5) (6)

Enzymatic method described by Oliver and modified by Rosalki and later by Szasz.

1) Creatine phosphate + ADP —**CK**→ Creatine + ATP

2) D-Glucose + ATP —**HK**→ ADP + G-6-Phosphate

3) G-6-Phosphate + NADP+ —**G6-PDH**→ 6-Phosphogluconate + NADPH + H+

The increase in absorbance, proportional to CK activity in the specimen, is measured at 340 nm.

REAGENTS (7)

R1 **CPK** Reagent 1	**DANGER**	
Imidazole Acetate, pH 6,3	120	mmol/L
HK (Hexokinase)	> 7500	UI/L
Magnesium acetate	12	mmol/L
D-Glucose	23	mmol/L
EDTA	2	mmol/L
AMP	7	mmol/L
NADP	2,2	mmol/L
Diadenosine phosphate	10	µmol/L
N-Acetyl-L-cysteine (NAC)	21	mmol/L

R2 **CPK** Reagent 2	**DANGER**	
Imidazole Acetate, pH 6,3	120	mmol/L
G-6-PDH	> 3500	UI/L
Creatine Phosphate	36	mmol/L
ADP	3	mmol/L
EDTA Na2	2	mmol/L

DANGER

Repro. 1B: H360 - May damage fertility or the unborn child

P201: Obtain special instructions before use, P202: Do not handle until all safety precautions have been read and understood, P308+P313: IF exposed or concerned: Get medical advice/attention, P405: Store locked up, P501: Dispose of contents/container in accordance with dangerous waste regulations. Classification due to Imidazole < 1%.

For more details, refer to Safety Data Sheet (MSDS)

REAGENTS PREPARATION

Ready for use.

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.

STABILITY AND STORAGE

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

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

Once opened:
- Separated reagents are stable at least 3 months.
- Discard any reagent if cloudy.

SPECIMEN COLLECTION AND HANDLING (1) (2)

Unhemolysed serum. Avoid anticoagulants such as heparin, EDTA, citrate or fluoride. Protect from light and store in an airtight container to prevent loss of CO_2. Adjunction of thiols is not necessary.

CK activity is stable in serum for:
- 4 to 8 h at room temperature
- 1 to 2 days at 2-8°C
- 1 month at –20°C

LIMITS (1) (3)

Discard any hemolyzed specimen (some enzymes and intermediate products released by erythrocytes interfere with the reaction).
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 INTERVAL (1) (2)

CK activity in serum is influenced by age, sex, origin, corpulence, physic activity and other less known genetic factors.

	IU/L (37°C)	µKat/L
Newborn and pediatric	145-1578 (Moy 382)	[2,47-26,85]
Alter caesarian births	2-3 x adult	
4 days	3 x adult	
6 weeks-12 years	Adult values	
Adult Men > 19 years	20-200 UI/L	[0,34-3,40]
Adult Women > 19 years	20-180 UI/L	[0,34-3,06]

Heterogeneity of serum CK activities have been described among racial groups; 97.5th percentiles were respectively as follows:

Population	IU/L
African-American Men	520
Caucasian Men	370
African-American Women	290
Caucasian Women	145

Normal Range can be assay and Instrument dependent.
Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES AT 37°C ON KENZA ONE

Refer to the application of analyzer used.

Linearity Range: between 25 and 1217 IU/L

Detection limit: approx. 0.1U/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	57	147	437
S.D. (IU/L)	1.3	2.1	4.2
C.V. %	2.3	1.5	1.0

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	58	146	430
S.D. IU/L	3.0	6.2	18.9
C.V. %	5.2	4.2	4.4

Comparison studies with commercially available reagent:

Realized on serum specimens (n=25) between 50 and 480 IU/L

y = 0.9426 x + 8.4 r = 0.9916

Analytical Sensitivity: approx. 0.005 abs/min for 10 IU/L

Interferences:

Turbidity	No interference up to 0.295 abs
Ascorbic acid	No interference up to 2390mg/dL
Total bilirubin	Negative interference from 228 µmol/L
Direct bilirubin	No interference up to 486 µmol/L
Hemoglobin	Negative interference from 19 µmol/L
Glucose	No interference up to 990 mg/dL

Other substances may interfere (see § Limits)

On the board stability: 3 months

Calibration Stability: 30 days

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

Stability and performances data on Kenza 240TX/ISE and Kenza 450TX/ISE are available on request.

CALIBRATION

- REF 95015 Multicalibrator (*traceable to internal Masterlot*)

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

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- 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

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 657-666, 728, 1185-1190.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 306-309*
(3) *p .3-185 to 3-190.*
(4) *Oliver I.T., Biochem J., **61**, (1955), p.116-122.*
(5) *Rosalki S.B., J. Lab. Clin. Med., **69**, (1967), p.696-705.*
(6) *Szasz G., Gruber W., and Bernt E., Clin. Chem., **22** (1976), p.650-656.*
(7) *Horder M and al, Approved IFCC recommendation on methods for the measurement of catalytic concentration of enzymes. Part 7. IFCC method for creatine kinase [EC 2. 7. 3. 2]. Eur J. clin. Chem. Clin. Biochem., 29, p435-456 (1991).*

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