BIOLABO
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ALKALINE PHOSPHATASE DEA Method

Reagent for quantitative determination of alkaline phosphatase activity [EC 3.1.3.1] in human serum and plasma.

I REF K1214	**R1** 2 x 16 mL	**R2** 1 x 8 mL
I REF K2214	**R1** 2 x 32 mL	**R2** 2 x 8 mL
I REF K4214	**R1** 2 x 40 mL	**R2** 1 x 20 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 quantitative determination of alkaline phosphatase activity in human serum and plasma.

GENERALITIES (1)

Alkaline phosphatase (ALP) is found in many tissues, including bone, liver, intestine, kidney, and placenta. ALP determined by usual biochemical methods reflects total serum levels and does not distinguish the source of the isoenzyme. Clinicians must therefore rely on other parameters of liver or other organ function or a more specific determination of ALP to assess its source.

PRINCIPLE (1) (4) (5)

Optimized method based on DGKC (German Society of Clinical Chemistry, 1972) and SCE (Scandinavian Society of Clinical Chemistry) recommendations.
In alkaline solution, ALP catalyzes the hydrolysis of p-nitrophenyl phosphate in p-nitrophenol and phosphate.
The rate of formation of p-nitrophenol, proportional to the ALP activity, is measured at 405 nm.

REAGENTS COMPOSITION

R1	**ALP**	Buffer	
D.E.A. (Diethanolamine) pH 10,4			1.0mmol/L
Magnesium Chloride			0.5mmol/L
Preservative			
R2	**ALP**	Substrate	
p-nitrophenyl phosphate			10mmol/L
Preservative			

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 (ratio 4:1)

STABILITY AND STORAGE

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

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- 2 separated reagents are stable at least 30 days.
- Discard reagent if cloudy or if reagent blank at 405 nm is > 0.800.

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolysed serum or heparinized plasma immediately refrigerated.

ALP activity is stable in the specimen for:
- 2-3 days at 2-8°C.
- 1 month at –25°C.

LIMITS (3) (6) (7)

Hemolysis interferes due to the high concentration of alkaline phosphatase in red cells .

Fluoride, oxalate, citrate and EDTA inhibit alkaline phosphate activity and should therefore not be used as anticoagulants

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

MATERIALS REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

REFERENCE INTERVALS (2)

at 37°C	Men (IU/L)	Women (IU/L)
20-29 years	100-320	70-260
30-39 years	90-320	70-260
40-49 years	100-360	80-290
50-59 years	110-390	110-380
60-69 years	120-450	110-380
> 69 years	120-460	90-430

Children: Values may be increased (up to threefold during puberty)

Example of values given for information: 245-768 IUI/L à 37°C

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

PERFORMANCES

On Kenza One at 405 nm, 37°C

Detection limit: 0.1 IU/L

Linearity Range: between 66 and 1673 IU/L

Precision:

Within-run N = 20	*Level 1*	*Level 2*
Mean (IU/L)	181	420
S.D. IU/L	3.9	10.6
C.V. %	22	2.5

Between run N = 20	*Level 1*	*Level 2*
Mean (IU/L)	177	404
S.D. IU/L	6.3	1.4
C.V. %	6.0	2.6

Analytical sensitivity: approx. 0.009 abs/min for 10 IU/L

Comparison studies with commercially available reagent:
Realized on serum specimens (n=50)

y = 1.025 x – 1,105 r = 0,9997

Interferences:

Turbidity	Negative interference from 0.295 OD
Ascorbic acid	No interference up to 2500 mg/dL
Total bilirubin	Negative interference from 418 µmol/L
Direct bilirubin	No interference up to 486 µmol/L
Hemoglobin	Negative interference from 133 µmol/L
Glucose	No interference up to 990 mg/dL

Other substances may interfere (see § Limits)

On-board stability: 2 separate reagents are stable 14 days

Calibration Frequency: 14days

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 240TX/ISE, Kenza 450TX/ISE and Kenza One 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. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 676-684 and p.1429-1431.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 80-83*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-26 to 3-35*
(4) *Scandinavian Journal of clinical and laboratory investigation (1974), vol.33, p.291-306*
(5) *Recommendations of the German Society for Clin. Chemistry Z .Klin. Chem. Klin. Biochem. (1972), 10, p.290-291*
(6) *Wenger C. et al. Alkaline phosphatase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1094-1098.*
(7) *Rosalki S et al. Clin Chem 1993; 39/4: 648-652.*

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