BioMed-Alkaline Phosphatase

Kinetic method

REF: ALP101090 (6×15 ml)
REF: ALP 101050 (5 x10 ml)

INTENDED FOR USE:

For the quantitative determination of Alkaline phosphatase in serum.

PRINCIPLE:

Present kinetic method is optimized in accordance with German Clinical Chemistry Department (D.G.K.C.) recommendations.
Alkaline phosphatase catalyzes the hydrolysis of p-nitrophenyl phosphate in p-nitrophenol and phosphate, in alkaline medium,

$$\text{p-nitrophenyl phosphate} + H_2O \xrightarrow{ALP} \text{p-nitrophenol} + H_3PO_4.$$

Alkaline phosphatase (ALP) activity in sample is determined by measuring the per time absorption increase at 405 nm.

SPECIMEN COLLECTION:

Non hemolized serum or plasma (heparin)
Notes:
ALP activity is inhibited by EDTA anticoagulants, oxalates, and citrates.
ALP in serum is reported stable up to 2 days in refrigerator (+2-8 °C).
Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENTS COMPOSITION:

R1	Buffer DEA Magnesium ions	10-20% <1%
R2	p-nitrophenyl phosphate	10mmol/L

PACKAGE: Collection and storage.

Store in refrigerator (+2-8°C.).
Stable until the expiration date reported on the package.
After the unsealing and the taking of the reagent ,it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination.

PRECAUTIONS & WARNING:

Avoid pipette with mouth.
The Reagent (R1) contains: diethanolamine, and according to current regulation, is classified as:
Xn- Harmful.
R41 - Risk of serious damage to eyes.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
The Reagent (R2), should not be considered as dangerous.
S Phrases: S22 - Do not breathe dust.
S24/25 - Avoid contact with skin and eyes.
On request is available a safety and precautions data form .
The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.
Anyway handle with care, avoid ingestion, avoid contact with eyes,skin and mucous membranes.
The samples must be handle as potentially infected from HIV or Hepatitis material.

REAGENT PREPARATION & STABILITY :

The reconstituted reagent is limpid and pale yellow.
Working reagent **: R1: 4 volumes + R2: 1 volume**
Mix well do not shake
Reagent (R1+R2) is stable 3 days at room temperature and 3 weeks if stored in refrigerator.

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations

PROCEDURE:

Wavelength:	405nm
Optical path:	1cm light path
Temperature:	+25/30/37°C
Reading:	Against distilled water
Assay Type:	Increasing kinetic

Pipetting in tubes:

	SAMPLE
Reagent(R1+R2)	1000 µL
Sample	10 µL

Adjust the instrument to zero with distilled water.
Mix, transfer in cuvette and incubate for 30 sec at 37°C; read sample increase and extinction at time after 60/120/180 sec.
Calculate ΔE/min. at 405nm.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.
For automated procedure, ask for specific application.

CALCULATION:

405nm ALP (U/L) = ΔE/min × 5454

EXPECTED VALUES:

	37°C	30°C	25°C
Adults	98-279 U/L	73-207 U/L	60-170 U/L
Children	250-775 U/L	185-575 U/L	151-471 U/L

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol.

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE:

MEASURE INTERVAL LINEARITY	1200 UI/L
DETECTION LIMIT:	15 UI/L
SENSITIVITY:	2 UI/L = 0.002ΔE/min.(405nm)

INTRA-ASSAY PRECISION: n=20

LOW LEVEL	M= 182 UI/L	C.V.=1.8%
MEDIUM LEVEL	M= 308 UI/L	C.V.=0.6%
HIGH LEVEL	M= 559 UI/L	C.V.=1.3%

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M= 186 UI/L	C.V.2.3%
MEDIUM LEVEL	M= 310 UI/L	C.V.1.2%
HIGH LEVEL	M= 569 UI/L	C.V.2.4%
CORRELATION	r = 0.999	n= 50
INTER.ANALIZED	113 – 689 UI/L	
LIN. REGRESSION	y = 0.998x - 2.9	n= 50

INTERFERENCE:

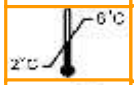
Interferences are negligible up to:			
Bilirubin	20mg/dL	Glucose	500 mg/dL
Triglicerides	1000mg/dL	Hemoglobin	4 g/L

METHOD LIMITATIONS:

Method for determination of Total Alkaline Phosphatase (ALP) activity in sample.
For concentration higher than 1500 U/L, repeat the measure on a sample diluted with physiological solution and multiply the results by dilution factor.
For a thorough evaluation of the interfering substances , consult :
Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

REFERENCES:

1. Tietz N.W. (ed), Fundamentals of Clinical Chemistry, W.B .Saunders Co., Philadelphia,1976.
2. Henry, R.J., Clinical Chemistry, Principles and Technics .Harper and Row Publishers. New York, 1964.
3. Young, D.S., et al., Clin Chem. 21(5),1972.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

EGY- CHEM for lab technology
Badr City, Industrial Area Piece 170
250 Fadan In East of Elrubaki, EGYPT
Office Tel: +202 26236727 / +202 26236598
Factory Tel: +202 23108170 / +202 23108171
Fax: +202 26240986
www.egy-chem.com

CE
EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany