

BioMed-Alkaline Phosphatase



Kinetic method

REF: ALP101090 (5x18 ml)

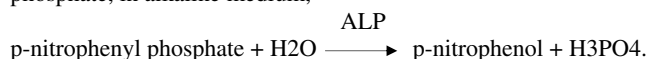
INTENDED FOR USE:

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,



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), powder, 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: 5 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 60 sec at 37°C; read sample increase and extinction at time 0 sec and after 60/120/180 sec.

Calculate $\Delta E/\text{min}$. 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) = $\Delta E/\text{min} \times 5454$

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.

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.

PERFORMANCE:

| | |
|-------------------|------------------------------|
| MEASURE INTERVAL: | 15 -1500 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.ANALYZED | 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 |
| Triglycerides | 1000mg/dL | Hemoglobin | 4 g/L |






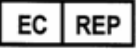



METHOD LIMITATIONS:

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).

| | |
|---|---|
|  | Consult Instructions for Use |
|  | Caution, consult accompanying Documents |
|  | In Vitro Diagnostic Medical Device |
|  | Temperature limitation |
|  | Manufacturer |
|  | Authorized Representative in the European Community |
|  | Catalogue number |
|  | Batch code |
|  | Use by |

| | |
|---|--|
|  Egy-Chem for lab technology Head Office: 83 Abdel-Hamid Badawy St.Heliopolise, Cairo, Egypt Tel :202- 26236727 / 202- 26236598 Fax :202- 26240986 Website: www.egy-chem.com E-mail: sales@egy-chem.com or sales@egy-chem.net |   MDSS GmbH Schiffgraben 41 30175 Hannover, Germany |
|---|--|