

Alkaline Phosphatase (PNPP/AMP Method)
For photometric determination of Alkaline Phosphatase (ALP) according to the recommendation of German of Clinical Chemistry.

ORDER INFORMATION

Table with 2 columns: Cat.no., Kit Information. Rows include LG121-100 and LG121-1000 with their respective reagent quantities.

REAGENT

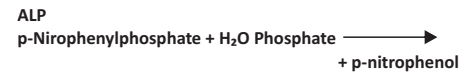
Reagent R1 : Buffer Reagent
Reagent R2 : Enzyme Reagent

SUMMARY

Alkaline phosphatase (ALP), a hydrolytic enzyme acting optimally at alkaline pH, exists in blood in numerous distinct forms which originate mainly from bone and liver, but also from other tissues as kidney, placenta, testes, thymus, lung and tumors.

PRINCIPLE

The increase in absorbance due to formation of 4-nitrophenolate is measured photometrically and is directly proportional to ALP activity in sample.



STORAGE INSTRUCTION AND REAGENT STABILITY

The reagent is stable up to the end of the indicated monthof expiry, if stored at 2°C– 8°C, protected from direct light andcontamination is avoided. Do not freeze the reagent.

COMPONENTS AND CONCENTRATIONS

Reagent: 2-Amino methyl propanol-36.5mL/L, Zinc sulphate-0.5gm/L, Magnesium acetate- 0.5 gm/L, p-Nitrophenylphosphate -6gm/L

WASTE MANAGEMENT

Please refer to local, national / international regulatory requirements.

REAGENT PREPARATION

Mix, 4 parts of reagent 1 and 1 part of reagent 2 = working reagent.
The stability of the working reagent is 5 days at 15°-25°C.
4 weeks at 2°- 8°C.
Reagent2 Protect the reaction solution from light.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L. General laboratory equipments.

SPECIMEN

- Serum, Heparin plasma / EDTA Plasma
Stability: Serum @ 2°- 8°C: 1 month
@ -20°C: 3 months
Only freeze once!
Discard contaminated specimens.

ASSAY PROCEDURE

Wavelength : 405nm
Temperature : 37°C

Table with 2 columns: Working Reagent, Sample. Rows show concentrations of 1000 µL and 20 µL.

Mix, incubate for 1 min. and read absorbance after every 60sec. for 120 sec. at 37°C.

CALCULATION

Note: ΔA/min and multiply by the corresponding factor from table below:

ALP activity U/L = ΔA/min x factor.(2764)

QUALITY CONTROL

For internal quality, normal and abnormal controls of Human Matrix should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

WARNINGS AND PRECAUTIONS

- The standard contains animal materials. Handle the products as potentially infections according to universal precautions and good clinical laboratory practices.
For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical & other findings.
Avoid direct contact with skin and do not swallow.
In very rare cases, samples of patients with gammopathy might give falsified results.
For Professional use only!

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

This test has been developed to determine Alkaline phosphatase concentrations within a measuring range from 3–1200U/L. When values exceed this range, samples should be diluted 1+1 with Na Cl solution (9 g/L) and the obtained result to be multiplied by 2.

LINEARITY / LIMIT OF MAX DETECTION

The higher limit of detection is 1200 U/L

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection of the assay is 3 U/L.

SPECIFICITY/INTERFERENCES

No interference was observed by Ascorbic acid up to 30mg/dL, Bilirubin up to 40mg/dL and Triglycerides up to2000mg/dL.

PRECISION

Table with 4 columns: Intra assay n=20, Mean (mg/dL), SD (mg/dL), CV (%). Rows show Sample 1, Sample 2, and Sample 3.

Table with 4 columns: Intra assay n=25, Mean (mg/dL), SD (mg/dL), CV (%). Rows show Sample 1, Sample 2, and Sample 3.

METHOD COMPARISON

A comparison of Precision Biomed Alkaline Phosphatase with commercially available assay (x) using 15 samples gave following results: y = y = 0.997x – 0.740; r2 = 0.997.

ASSAY PARAMETERS

Table with 2 columns: Mode, Kinetic. Rows include Wavelength (405 nm), Reaction slope (Increasing), Path length (10 mm), Temperature (37°C), Reagent (1000 µL), Sample (20 µL), Delay Time (60 seconds), Read Time (60 seconds), No. of Readings (2), Factor (2764), and Linearity (1200 U/L).

REFERENCE RANGE

Table with 3 columns: Adults, 30°C, 37°C. Rows show Women 20-25 years (U/L), Men 20-50 years (U/L), Women > 60 years (U/L), and Men > 60 years (U/L).

Table with 3 columns: Children, Male (37°C) U/L, Female (37°C) U/L. Rows show 1-30 Days, 1 Months -1 Year, 1 Year - 3 Year, 4 Year - 6 Year, 7 Year - 9 Year, 10 Year - 12 Year, 13 Year - 15 Year, and 16 Year - 18 Year.

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

LITERATURE

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- Johnson AM, Rohlfes EM, Silverman LM. Proteins InBurtis CA, Ashwood ER. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p.477-540.
- Thomas L. Clinical Laboratory Diagnostics. 1st ed.Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 652-6.
- Guder WG, Zawta B et al. The Quality of DiagnosticSamples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
- Dati F, Schumann G, Thomas L, Aguzzi F, BaudnerS,Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for Interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem1996;34:517-20.
- Young DS. Effects of Drugs on Clinical LaboratoryTests.5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.

INDEX OF SYMBOLS

Table with 4 columns: ISO 15185, International Organization or Standardization, Manufacturer, Expiry date, Lot (batch) number, Store between 2-8°C, Keep out of Sunlight, For invitro diagnostic use only, Read product insert before use, Do not use if package is damaged, Keep Away From Moisture.

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