

Alkaline Phosphatase Test Kit

REF	Pack Size	Reagent 1	Reagent 2
ALPLMS01	1x25 ml	1x20 ml	1x5 ml
ALPLMS02	2x25 ml	2x20 ml	2x5 ml
ALPLMS03	4x25 ml	4x20 ml	4x5 ml

INTENDED USE

Alkaline phosphatase reagent is used for the quantitative estimation of alkaline phosphatase in human serum or plasma.

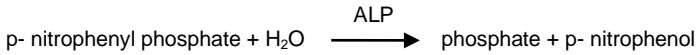
CLINICAL SIGNIFICANCE

Alkaline Phosphatase is a hydrolytic enzyme found in serum in numerous distinct forms which originate mainly from bone and liver. Physiological increases are found during bone growth in childhood and in pregnancy, while pathological increases are largely associated with hepatobiliary and bone diseases. Elevated activities are also observed in infectious hepatitis, bone disease, osteomalacia (rickets), bone metastases and hyperthyroidism.

METHOD

PNPP Method

TEST PRINCIPLE



KIT CONTENTS/COMPONENTS

Reagent 1: AMP buffer & Reagent 2: Substrate PNPP

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

SAFETY PRECAUTIONS AND WARNINGS

1. For in-vitro diagnostics use only.
2. Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3. Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION, STORAGE AND STABILITY

Mix 4 part of reagent 1 and 1 part of Reagent 2
(for making 1000 μL reagent mix 800 μL Reagent 1 and 200 μL Reagent 2)

REAGENT DETERIORATION

Discard the reagent if absorbance exceeds 1.2 against distilled water at 405 nm.

SPECIMEN

Serum, plasma (heparinate only), sera kept at room temperatures usually show a slight increase in activity, which varies from 1% over a 6-hour period to 3 to 6 % over a 1 to 4 days period. Even in sera stored at refrigerator temperature, activity increases slowly. In frozen sera, activity decreases but slowly recovers after thawing the serum. EDTA, Citrate, and Oxalate is not suitable because of inhibition of ALP activity.

PROGRAM

Reaction Mode	Kinetic
Wavelength	405 nm
Light Path	10 mm
Reagent Volume	1000 μL
Sample Volume	20 μL
Delay Time	60 secs.
Interval Time	60 secs.
Factor	2720
Linearity	1400 U/L

Pre warm the required amount of the working solution at temperature 37°C before use.

PROCEDURE

Pipette into Cuvette / Flow cell:	
Reagent volume	1000 μL
Sample volume	20 μL

Mix & incubate for 60 sec. at assay temperature, read the first reading at 60 seconds and subsequently two more readings with 60 seconds interval at 405 nm.

CALCULATION

Alkaline phosphatase (U/L) = $\Delta \text{Abs./min} \times \text{Factor}$
Factor = 2720 if reading is taken at 405 nm.

NORMAL VALUES

	Male	Female
Adult	41-137	39-118
Child	79-446	

LIMITATIONS

If the value exceeds 1400U/L, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator or the Standard included, calibrate the assay.

1. When using a new reagent or lot
2. When QC values are out of range

WASTE DISPOSAL










This Product is made to be used in professional laboratories.

HIGHLIGHT

1. The Reagents are sensitive to light & higher temperature. Reagents may develop a slight yellow coloration on ageing which does not interfere with the functionality of reagent.
2. If the volume of the reagent is not sufficient to fill the cuvette, double all the specified volumes.
3. Storage condition mentioned on the kit is to be maintained.
4. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
5. Before testing bring the reagents to the specified temperature.
6. Avoid reagents contamination.
7. Every time use new pipette-tips for pipetting out the reagents.
8. These Reagent kits meant for laboratory / professional use only, not for Drug use.

REFERENCES

Henry, R.J., "ENZYMES" in Clinical Chemistry Principle and Techniques, Harper and Row Publishers, New York, 815 (1974)
Lords Data File.

	Catalog No.		Contain Sufficient for test
	Batch No.		Instruction for use
	Manufacturing Date		In-vitro Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/ALP/01 Rev.: 03; Rev Dated.: 22/07/2024

