

LiquiMAX Alkaline Phosphatase - SLR

IFCC Method / AMP Buffer

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVALP1 - 25	5 x 5 ml	Single Liquid Reagent
AVALP1 - 50	5 x 10 ml	Single Liquid Reagent

INTENDED USE:

Kit is use for the quantitative determination of alkaline phosphatase (ALP) in human serum.

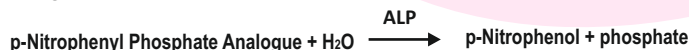
PRODUCT FEATURES:

- Liquid Stable, Ready to use Mono Reagent
- PNPP Analogue used for better stability
- 3 Minutes increasing kinetic reaction (60Sec Delay+120 Sec Measuring)
- Measuring Wavelength 405 nm
- Kinetic factor 2764 at 37° C.
- Linearity 1250 IU/L
- Serum is the only specimen
- Available as multipurpose reagents and dedicated system packs

CLINICAL SIGNIFICANCE

Alkaline phosphatase in serum consists of four structural genotypes: the liver-bone-kidney type, the intestinal type, the placental type and the variant from germ cells. It occurs in osteoblasts, hepatocytes, kidneys, spleen, placenta, prostate, leukocytes and the small intestine. The liverbone-kidney type is particularly important. A rise in the Alkaline Phosphatase activity occurs with all forms of cholestasis, particularly with obstructive jaundice. It is also elevated in diseases of the skeletal system, such as Paget's disease, hyperparathyroidism, rickets and osteomalacia, as well as with fractures and malignant tumors. A considerable rise in the Alkaline Phosphatase activity is sometimes seen in children and juveniles. It is caused by increased osteoblast activity following accelerated bone growth. Various reference values for the purposes of clinical evaluation have been assigned to differing age groups. In 1946, Bessey, Lowry and Brock published a method for the determination of Alkaline Phosphatase using p-nitrophenyl phosphate as substrate buffered with glycine/NaOH. This assay described here meets the IFCC recommendations and uses AMP buffer.

PRINCIPLE :



STORAGE & STABILITY

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the label.

KIT COMPONENTS

- ALP Substrate Reagent

COMPOSITION

AMP	pH 9.7	3.5 Mol/l
Magnesium chloride		0.6 mMol/l
p-Nitrophenylphosphate Analogue		0.070 mMol/l
Sodium Azide		0.10 %
Zinc Sulphate		0.3 mMol/l

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

- Discard any turbid reagent if reagent absorbance exceeds 1.4 at 405 nm against distilled water.
- Keep the standard vial plugged after use, in order to avoid deterioration.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP guidelines.

SPECIMEN COLLECTION & STORAGE

- Unhemolysed serum is the preferred specimen. DO NOT USE PLASMA
- Serum samples are stable for 24 hours at 2-8°C and for a month at -20°C. Please note that ALP activity in serum stored at 2-8°C increases with time.

SYSTEM PARAMETERS:

Reaction type (mode)	:	kinetic	:
Reaction direction	:	increasing	
Wave length	:	405 nm	
Flow cell temp.	:	37°c	
Zero setting with	:	distilled water	
Delay time	:	60 seconds	
Measuring time	:	120 seconds	
Reagent volume	:	500 µl	
Sample volume	:	10 µl	
Factor	:	2764	
Linearity	:	1250	
Units	:	IU/L	

TEST PROCEDURE

Reagent	Sample/Control
Reagent	500 µl
Serum/Control	10 µl

Mix well and aspirate in to the analyzer. After 60 Sec Incubation (Delay) measure the change of optical density during the next 120 seconds (Measuring Time) against distilled water at 405 nm as follows.

Ao- Exactly after 60 Seconds.

A1, A2 Exactly after 60 seconds during next 120 seconds.

CALCULATION

Calculate the average change in absorbance per minute ($\Delta A/\text{min}$) and multiply by the corresponding factor.

ALP activity [IU/L]: $\Delta A/\text{min} \times 2764$

EXPECTED VALUES:

As per the recommendations of International Liver Foundation the following reference values are assigned for ALP IFCC Assays. But it is for the Laboratory to establish its own reference values.

20-50 Y	Male:	53-165 U/L
	Females:	53-165 U/L
≥60 Y	Male:	56-136 U/L
	Females:	53-160 U/L

In growing children (Age ; 10-17 Years) the values will be Higher than adults i.e.350 - 585 IU/L.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

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

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 1250 IU/L

2. Sensitivity/ Limit Of Detection (LOD)

The lower limit of detection is 2 IU/L

3. Interferences

No interference is absorbed by triglycerides up to 2200 mg/dl, bilirubin up to 42 mg/dl, hemoglobin up to 150 mg/dl, intra lipids up to 1200 mg/dl and ascorbic acid up to 32 mg/dl

4. PERFORMANCE CHARACTERISTICS

Precision

Intra-assay precision	mean	SD	CV
N=20	(IU/L)	(IU/L)	(%)
Sample 1	143.1	2.30	1.59
Sample 2	448.4	6.60	1.46
Sample 3	449.2	5.90	1.32

Inter-assay precision	mean	SD	CV
N=20	(IU/L)	(IU/L)	(%)
sample 1	142.2	2.1	1.59
sample 2	448.3	6.67	1.47
sample 3	449.5	5.97	1.35

Method Comparison

A comparison of the LiquiMAX ALP - SLR (y) with a commercial obtainable assay (x) gave following results with 80 samples.

$$y = 0.992x + 2.64; r = 0.991$$

LIMITATIONS

The test has been developed to determine Alkaline Phosphatase activities which correspond to maximal A/min of 0.452

If such value is exceeded the sample should be diluted 1+9 with NaCl solution (9g/l) and the results be multiplied by 10.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














Notes

- Avoid contact with skin and mucous membranes. The reagents contain sodium azide as preservative. Do not swallow.
- During the reaction p-nitrophenol is produced. This substance is poisonous when inhaled, swallowed or when absorbed through the skin. If the reaction mixture comes into contact with skin or membranes, wash copiously with water and consult a doctor.
- When the reagent is stored properly at 2-8°C and the contamination is avoided, it is stable up to the expiry date mentioned on the labels and kit box.
- It is recommended that when the reagent is not in use, it should be strictly kept at 2-8°C for better performance and stability.
- Substrate Reagent must be protected from direct sun light.
- Do not expose the reagent to high temperatures above 10°C.

REFERENCES

- Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790.
- Bessey OAH et al. J Biol Chem 1946;164:321
- Empfehlungen der Deutschen Gesellschaft für Klinische Chemie. Standard-Methode zur Bestimmung der Aktivität der alkalischen Phosphatase. Z klin Chem u klin Biochem 1972;10:191.
- Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-474.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



Manufactured in India by :

AVECON™ Healthcare Pvt. Ltd.
Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha, Ambala, Haryana (INDIA)-133104

E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875