Alkaline Phosphatase Test Kit

REF	Pack Size	Reagent 1	Reagent 2
ALPLMA01	5 X 20 + 5 X 5ml	1 x 20 ml	1 x 5ml

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

CLINICAL SIGNIFICANE
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, osteornalacia (rickets), bone metastases and hyperthyroidism

METHOD
IFCC (AMP) Method

TEST PRINCIPLE

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

KIT CONTENTS/COMPONENTS
Reagent 1 : AMP buffer
Reagent 2 : Substrate PNPP

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1015-200TPH.
Calibrator
Controls.

REAGENT STORAGE, STABILITY AND HANDLING
Reagent is ready to use & are stable up to expiry date mentioned on the pack.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

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.

APPLICATION For LM1015-200 TPH

Method	Kinetic
Reaction	Increasing
Primary filter	405
Secondary filter	NO
R1 Volume	240
R1 Position	*
Incubation time (Sec)	144
R2 Volume	60
R2 Position	*
Incubation time (Sec)	60
Sample Volume	6
Read Time	180
Calibrator Concentration	As per vial label
Mix speed set	Middle
Unit	U/L
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Alkaline Phosphatase concentration of each sample.

NORMAL VALUES

	Male	Female
Adult (U/L)	41-137	39-118
Child (U/L)	79-446	

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

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

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

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (U/L)	109.1	539	108.6	541
SD	1.79	1.83	1.80	1.80
CV (%)	0.02	0.01	0.02	0.01

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturing Date		Storage temperature
	Expiry Date		Manufacturer

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