Alkaline Phosphatase Test Kit
(Kinetic UV, Optimized IFCC method)

Quantitative determination of Alkaline Phosphatase in human Serum / Plasma / other body fluids
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
ALPMONO 25	25 X 1 ml
ALPMONO 50	50 X 1 ml
ALP 25	1 X 25 ml
ALP 50	1 X 50 ml
ALP 100	1X100 ml
ALP 125	5X25 ml
ALP 1000	1X1000 ml
ALP 5000	1X5000 ml
ALP 10000	1X10000 ml

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, osteornalacia (rickets), bone metastases and hyperparathyroidism.

Method
Kinetic photometric test, according to the International Federation of clinical Chemistry and Laboratory Medicine (IFCC).

PRINCIPLE
Alkaline phosphatase (ALP) catalyses the hydrolysis of p-nitrophenyl phosphate at alkaline pH, liberating p-nitrophenol and phosphate, The rate of p-Nitrophenol formation, measured photometrically, is proportional to the catalytic concentration of alkaline phosphatase present in the sample.

REAGENT
Reagent : ALP Substrate Reagent

REAGENT PREPARATION
The reagent supplied is ready to use.

REAGENT STORAGE AND STABILITY
The reagent is stable till the expiry when stored properly at 2 - 8°C and protected from direct sunlight.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum: Use non - haemolysed serum.
Plasma: Use heparin. Do not use EDTA, Oxalate or Fluoride.
Do not use hemolytic samples!
Stability:
7 days at 4 – 8 °C
2 months at –20 °C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against distilled water
Reaction Type	Kinetic test
Reaction Direction	Increasing
Sample Volume	20 µl
Reagent Volume	1000 µl
Delay/Lag/time	60 Secs
Interval time	30 Secs
No. of Readings	04
Blank Absorbance limit	< 0.85
Factor	2720
Low Normal at 37°C	25 IU/L
High Normal at 37°C	147 IU/L
Linearity at 37°C	2000 IU/L

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

Sample	20 µl
Reagent	1000 µl

Mix well and Incubate at 37°C for 60 secs. Measure absorbance, increase every 30 sec for 2 minutes and determine the Δ A/min.

SAMPLE DILUTIONS
- The method is linear to a concentration of 2000 IU/L.
- If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

CALCULATION
Results are calculated, usually automatically by the instrument, as follows:

A/min. x 2720 = U/l Alkaline Phosphatase

CLIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.
This method is traceable to the molar extinction coefficient.
It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox Control 2	206.73	3.41	1.65%
Randox Control 3	339.97	3.28	0.97%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox Control 2	209.50	2.05	0.98%
Randox Control 3	344.59	2.89	0.84%

LINEARITY
The method is linear to a concentration of 2000 IU/L.

If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

Limit of detection: The limit of detection for Alkaline Phosphatase is 2U/L.

METHOD COMPARISON

A comparison of Alkaline Phosphatase with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

ADULTS	25-147 IU/L
Children	
Aged 1 day	< 250 IU/L
Aged 2-5 day	< 231 IU/L
Aged 6 day – 6 Months	< 449 IU/L
Aged 7Months-1 Year	< 462 IU/L
Aged 1-3 Year	< 281 IU/L
Aged 4-6 Year	< 269 IU/L
Aged 7-12 Year	< 300 IU/L
Aged 13-17 Year	< 390 IU/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 40mg/dl.
- Hemoglobin: No interference found upto Hemoglobin 400mg/dl.
- Lipemia: No interference found upto 900mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

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3. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third Edition 1990: 3: 19-25.
4. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis (4th Ed.) Burtis, Ashwood & Bruns (Eds), Elsevier Saunders, 2005; 2290

6) Bakker A.J. et. al. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9), 1240 - 1243

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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