SBio ALKALINE PHOSPHATASE KIT

(Mod. Kind & King's Method)

(For invitro diagnostic use only)

REF	90162115	90172130
Σ	15 Tests	30 Tests

CE

8°C / 2°C Store at 2-8°C	Manufacturer	This way up	Mod Kind & King's — Mod. Kind & King's Method	
Use by (Last day of stated month)	Consult Instructions for use	L1 Buffer Reagent	L2 Substrate Reagent	
Date of Manufacture	REF Catalogue Number	S Phenol Standard (10 mg/dl)	L3 Colour Reagent	
LOT Batch Number	IVD *In vitro* Diagnostic Medical Device	Σ Contains sufficient for <n> tests	EC REP Authorised Representative in the European Community	

INTENDED USE

Alkaline Phosphatase Kit is used for the determination of Alkaline Phosphatase Activity in serum.

PRINCIPLE OF THE TEST

Alkaline Phosphatase at an alkaline pH hydrolyses di Sodium Phenylphosphate to form phenol. The Phenol formed reacts with 4-Aminoantipyrine in the presence of Potassium Ferricyanide, as an oxidising agent, to form a red coloured complex. The intensity of the colour formed is directly proportional to the activity of Alkaline Phosphatase present in the sample.

di Na. Phenylphosphate + H_2O —(Alkaline Phosphatase, pH 10.0)→ Phenol + di. Na. Hydrogen Phosphate

Phenol + 4 - Aminoantipyrine —(Alkaline Medium, $K_3Fe(CN)_6$)→ Red Coloured Complex

CLINICAL SIGNIFICANCE

Alkaline phosphatase is produced primarily in the liver and in bone. It also is produced by the placenta of a pregnant woman and, to a lesser extent, by the intestines and kidneys. Normally, the liver produces more Alkaline phosphatase than the other organs or the bones. Some conditions can release large amounts of Alkaline phosphatase into the bloodstream. These conditions include rapid bone growth (during puberty), bone disease (osteomalacia or Paget's disease), or damaged liver cells. An Alkaline phosphatase test measures the amount of the enzyme Alkaline phosphatase in the blood.

PRESENTATION	15 Tests	30 Tests
L1: Buffer Reagent	60 ml	120 ml
L2: Substrate Reagent	6 ml	12 ml
L3: Colour Reagent	60 ml	120 ml
S: Phenol Standard (10 mg/dl)	5 ml	5 ml

COMPOSITION

Carbonate Buffer 100mmol; pH10.0; Disodium Phenyl Phosphate > 50mmol; Amino Antipyrine > 70mmol ; Non Reactive Stabilizers, Detergents and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8° C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum which is free from hemolysis is required.

REAGENT PREPARATION

All the reagents are ready to use.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter	:	510 nm (Hg 546 nm) / Green
Temperature	:	37° C
Light path	:	1 cm

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Assay:

Pipette into four clean dry test tubes labeled as Blank (B), Standard (S), Control (C) and Test (T).

Addition of Reagent	B (ml)	S (ml)	C (ml)	T (ml)
Distilled Water	1.05	1.00	1.0	1.0
Buffer Reagent (L1)	1.0	1.0	1.0	1.0
Substrate Reagent (L2)	0.10	0.10	0.10	0.10
Mix well and allow to stand at 37°C for 3 minutes and add				
Sample	-	-	-	0.05
Phenol Standard (S)	-	0.05	-	-
Mix well and allow to stand at 37°C for 15 minutes and add				
Colour Reagent (L3)	1.0	1.0	1.0	1.0
Sample	-	-	0.05	-

Mix well after each addition. Measure the absorbance of the Blank (Abs.B), Standard (Abs.S), Control (Abs.C) and Test (Abs.T) against distilled water.

CALCULATIONS

$$\text{Total Alkaline Phosphatase activity in K.A. Units} = \frac{\text{Abs.T - Abs.C}}{\text{Abs.S - Abs.B}} \times 10$$

QUALITY CONTROL

The following process is recommended for QC during the assay of ALP.

*Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

If Enzyme activity exceeds 60 K.A. Units dilute the sample with distilled water and repeat the assay. Multiply the value with the proper dilution factor.

Interferences:

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

Method comparison:

Comparative studies were done to compare our reagent with another commercial ALP Assay. No significant differences were observed. Details of the comparative study are available on request.

REFERENCE RANGE

Total Alkaline Phosphatase Activity : 3.0 - 13.0 K.A. Units

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTE

Alkaline Phosphatase is reported to be stable in serum for 3 days at 2-8° C. In case of multiple samples to be assayed **simultaneously**, only one Blank and Standard can be run for the entire series, however for each sample a Control and a Test assay has to be run additionally. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

(1) Kind, P.R.H., & King, E.J., (1954), J. Clin. Path., 7 : 322. (2) Varley, H., (1975) Practical Clinical Biochemistry, 4th Ed. (3) Data on file: Global invitro LLP.

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EC REP

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