ALKALINE PHOSPHATASE (S.L)

2 x 10 mL, 2 x 30 mL, 2 x 50 mL
11401001, 11401005, 11401003

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of Alkaline Phosphatase in serum or plasma.

- DGKC – SCE recommended procedure
- Linear upto 700 U/L
- Working reagent can be prepared as per requirement
- Pack sizes to suit all types of laboratories

CLINICAL SIGNIFICANCE

Alkaline phosphatase (ALP) is widely distributed throughout the body, but clinically important one for diagnostic reasons are in bone, liver, placenta & intestine. Growing bone is associated with the release of ALP and so in childhood the level of ALP is around 3 times of that of adult. During pregnancy in 2nd & 3rd trimester the enzyme rises considerably due to placenta releasing ALP. It can be used to examine placental function.

Elevated levels are seen in bone diseases, e.g. pagets disease, rickets, osteoblastic metastatic & in obstructive disease of biliary tract.

Decreased levels are rarely seen. e.g. in Vitamin A resistant rickets.

PRINCIPLE

Kinetic determination of ALP according to the following reaction

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

ALP = Alkaline Phosphatase

REAGENT COMPOSITION

ALKALINE PHOSPHATASE(S.L) R1	**2 x 8 mL /2 x 24 mL / 2 x 40 mL**
Diethanolamine Buffer (pH 10.2)	125 mmol/L
Magnesium Chloride	0.625 mmol/L
ALKALINE PHOSPHATASE (S.L) R2	**2 x 2 mL/2 x 6 mL / 2 x 10 mL**
P-Nitrophenyl phosphate	50 mmol /L

STORAGE AND STABILITY

The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8°C.

LINEARITY

The reagent is linear, upto 700 U/L.

If the concentration is greater than linearity (700 U/L), dilute the sample with normal saline & repeat the assay. Multiply the result with dilution factor.

NORMAL RANGE

It is recommended that each laboratory establish its own reference values. The following value may be used as guide line.

Women	:	64 - 306 U/L
Men	:	80 - 306 U/L
Children	:	180 - 1200 U/L

PREPARATION AND STABILITY OF WORKING REAGENT

Mix 4 volume of Reagent 1 (R1) with 1 volume Reagent 2 (R2)

The working reagent is stable for 30 days at 2-8°C.

Note : Discard the working reagent if the blank absorbance exceeds 1.00 at 405 nm.

PRECAUTION

To avoid contamination, use clean laboratory wares. Avoid direct exposure of working reagent to light.

SAMPLE

Serum / plasma (free of haemolysis)

GENERAL SYSTEM PARAMETER

Mode of Reaction	Kinetic
Slope of reaction	Increasing
Wavelength	405 nm
Temperature	37°C
Factor	2750
Blank	DI water
Linearity	700 U/L
Delay time	60 sec
No of readings	3
Interval	60 sec
Sample volume	20 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

LABORATORY PROCEDURE

Working reagent	1000 µL
Sample	20 µL

Mix and incubate at 37°C for one minute. Measure the change in absorbance per minute (ΔOD/min) during 3 minutes.

CALCULATION

ALP Activity (U/L) = (ΔOD / min.) x 2750

BIBLIOGRAPHY

1. Schlebusch, H., et al.; Dtsch .Med. Wschr. 99, 765 (1974)
2. Z. Klin. Chem. Klin Biochem. 8,658 (1980) 10, 182 (1972)

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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