Instructions For Use

GENESIS

Alkaline Phosphatase (DGKC Method (4+1))

Cat no.	size
1201 101	5*10
1201 102	5*20
1201 103	10*10
1201 104	2*25

INTENDED USE

Alkaline Phosphatase Reagent is intended for the in vitro Quantitative diagnostic determination of ALP in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Alkaline Phosphatase catalyses the hydrolysis of naturally occurring and synthetic substrates. The natural substrates upon which they act in the body are not known. The enzyme consists of 4 structural genotypes and is present in a variety of tissues including bone, liver, intestine, placenta, kidney and spleen. 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, hyper-parathyroidism, 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.

PRINCIPLE OF THE METHOD

In the presence of magnesium and zinc ions, p-nitrophenyl phosphate is hydrolyzed by phosphatases to form phosphate and p-nitrophenol. The p-nitrophenol released is proportional to the ALP activity and can be measured photometrically

p-Nitrophenyl-Phosphate + H_2O $\xrightarrow{ALP}$ p-Nitrophenol- + Phosphate

COMPOSITION

Reagent (R1)	Diethanolamine buffer, pH 9.8 Magnesium Chloride Detergents and stabilizers	1.0 mol/L 0.6 mmol/L >0.1%
Reagent (R2)	p - nitrophenylphosphate	2.0 mmol/L

STORAGE

Store at 2 - 8°C

The reagent is stable until expiration date stated on vial label.

REAGENT PREPARATION

Working reagent: (4) Parts of R1 are mixed with(1) part of R2.

Working reagent is stable for 3 weeks at 2 - 8 °C .

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC

− Analyzer, spectrophotometer able to read at 405nm.

SPECIMEN.

1.Use serum or heparin plasma, free of haemolysis, as specimen.

2.Do Not Use Citrate, Oxalate and EDTA.

3.Stability:-

2 months at -20 °C
4 weeks at 2 - 8 °C
7 days at 20 - 25 °C

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Mode : kinetic
Wavelength: 405 nm
Cuvette: 1 cm light path
Temperature: 37ºC
Delay time: 30 sec
Measuring time: 180 sec

3. Adjust the instrument to zero with distilled water or air.
4. Pipette into a cuvette:

Working reagent	1.0 ml
sample	20 µL

5. Mix and incubate for 30 seconds.
6. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals there after for 3 minutes.
7. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

$$ALP(U/l) = \triangle A/min \times 2750$$

REFERENCE VALUES

Children (1-14 year)	< 645 U/L
Adults	98 – 279 U/L

QUALITY CONTROL

It is recommended to use the Control Serum level Iand II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

− Detection limit: 1.6 U/L = 0.027 µkat/L.

− Linearity limit: 900 U/L = 15.0 µkat/L.

For higher values dilute sample **1/5** with physiological saline and repeat measurement**.**

− Repeatability (within run):

Mean Concentration	CV	n
117 U/L = 1.95 µkat/L	1.1 %	20
431 U/L = 7.18 µkat/L	0.7%	20

− Reproducibility (run to run):

Mean Concentration	CV	n
117 U/L = 1.95 µkat/L	4.5 %	25
431 U/L = 7.18 µkat/L	2.2%	25

− Interferences:

Lipemia (triglycerides < 10 g/L) and bilirubin (< 20 mg/dL) do not interfere**.**

BIBLIOGRAPHY

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CE

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