AGD

CliniPak

ALKALINE PHOSPHATASE

(PNPP / AMP Kinetic)

Code	Pack Size
AGDSP-AP50	R1-2 X 20 mL R2 - 2 X 5 mL
AGDSP - AP40	R1-2 x 16mL R2-2 x 4mL
AGDSP - AP145	R1-5 x 23mL R2-5 x 6mL

INTENDED USE

This reagent kit is intended for in vitro quantitative determination of Alkaline Phosphatase in serum.

CLINICAL SIGNIFICANCE

Alkaline Phosphatase is a membrane bound enzyme present in most tissues, bone, liver, intestinal epithelium, kidney,placenta and breast.It is a phosphatase of presumed bone origin.Therefore, Alkaline Phosphatase is high in infancy, childhood, adolescence and pregnancy.

Increased levels: are observed in drug therapy, hepatitis, biliary obstructions,bone diseases like rickets and paget's diseases, hyperparathyroidism, etc.

Decreased levels: are observed in severe anaemia, scurvy, kwashiorkor, and cretinism.

PRINCIPLE

Alkaline Phosphatase hydrolyses p-Nitrophenyl Phosphatase (PNPP) into p-Nitrophenol and phosphate. The alkaline pH of the buffered medium, p-Nitrophenol is yellow.The colour developed due to hydrolysis is measured at 405nm and is proportional to the Alkaline Phopsphatase activity. p-Nitrophenyl Phosphatase activity.

p-Nitrophenyl Phosphate+H2O $\xrightarrow{\text{ALP}}$ p-Nitrophenyl + Phosphate

PROCEDURE

Reagent 1 + Incubation + Sample

(240µL) (60sec) (6µL)

Reagent 2 $\longrightarrow$ Measurement

(60µL) (120Sec) (405nm)

REAGENT COMPOSITION

REAGENT 1

2-Amino 2- Methyl-propanol(AMP)	≈ 0.32 mmol/L
Zinc Sulphate	≈ 1 mmol/L
Magnesium Acetate	≈ 4 mmol/L
Preservatives, Stabilizers	Q.S.

REAGENT 2

PNPP	≈ 10 mmol/L

REAGENT STORAGE AND STABILITY

Alkaline Phosphatase is single reagent ready to use. The reagents are stable till the expiry date stated on the bottle label when stored at 2-8°C and protected from light.

SAMPLE

Preferably serum samples can be used, plasma can also be used. Citrate,oxalate,EDTA etc .should not be used as they inhibit the activity of alkaline phosphatase.

BASIC PARAMETER

SHORT NAME	ALP
NAME	ALKALINE PHOSPHATASE
METHOD	PNPP/AMP KINETIC
ASSAY	KINETIC (RATE A)
MAIN WAVE	405nm
SUB WAVE	0
DECIMAL	2
UNIT	IU/L
R1 VOLUME	240µL
INCUBATION	60 secs
R2 VOLUME	60µL
SAMPLE VOLUME	6µL
INCUBATION	0
MIXING SPEED	0
REACTIONTIME(Delay)	60 secs
CHECK TIME (Read)	60 secs
LINEAR RANGE	1600
ABSORBANCE RANGE	0-2.5
LINEARITY LIMIT	40
SUBSTRATE SHORTAGE	> 2.0
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

*Enter calibrator value as per the lot of calibrator and method.

LINEARITY

Reagent is linear up to1600IU/L.
Dilute the sample appropriately and re-assay if alkaline phosphatase concentration exceeds 1600 IU/L.Multiply result with dilution factor.

REFERENCE NORMAL VALUE

Children:104-390 IU/L
Adults :25-140IU/L

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhere, as any change to it affects the factor.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

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