SyRe

TBA™-25FR

AGAPPE

ALKALINE PHOSPHATASE IFCC

4 x 28/ 2 x 15 mL
12012065

Intended Use

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

- Kinetic Method recommended by IFCC
- Linear up to 2000 U/L
- Working reagent can be prepared as per requirement
- Pack sizes suit to 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 and 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 and 3rdtrimester 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. Paget's disease, Rickets, Osteoblastic metastatic and in obstructive disease of biliary tract.

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

Principle

Alkaline phosphatase acts in highly alkaline pH in presence of divalent Mg ions where it catalyses the hydrolysis of p-Nitrolphenylphosphate (PNPP) which results in release of p-Nitrophenol and free phosphate group. Absorbance is proportional to the serum alkaline phosphatase at 405 nm.
The enzyme alkaline phosphatase hydrolizes the 4-NPP to release 4-nitrophenol, under alkaline conditions. The 4-nitrophenol formed is detected spectrophotometrically at 405 nm to give a measurement of alkaline phosphatase activity in the sample.

$$\text{Para-nitrophenyl phosphate} + H_2O \xrightarrow[\text{pH 10.2, } Mg^{++}]{ALP} \text{p-nitrophenol} + \text{inorganic phosphate}$$

Kit Components

Reagent/ Component	Product Code 12012065	Description
Reagent 1(R1)	4 x 28 mL	HEDTA 8.78g/L zink sulfate 6mL/L Magnesium acetate-5g/L AMP buffer 92.6
Reagent 2 (R2)	2 x 15 mL	P-Nitro phenyl phosphate 50mmol/L

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation

Alkaline Phosphatase IFCC reagents are ready to use.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2-8°C and protected from light.

Open Vial Stability

Once opened the reagent is stable up to 4 weeks at 2- 8°C, if contamination is avoided

On-board Calibration Stability

Calibration is stable for 7 days.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagents.

Precaution

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

Waste Management

Reagent must be disposed off in accordance with local regulation.

Sample

Serum / plasma (Free of hemolysed sample)

Interferences

No interference for

Bilirubin up to	10 mg/dL
Haemoglobin up to	1000 mg/dL
Ascorbic Acid up to	50 mg/dL

Materials provided

Alkaline Phosphatase R1 & Alkaline Phosphatase R2.

Reagents required but not provided

Multicalibrator (Product Code: 11610002), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Calibration

Agappe Multicalibrator (Product Code: 11610002) is recommended for calibration of the assay.

Quality Control

It is recommended to use Agappe Qualicheck Norm and Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

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

Women	: 35 – 104 U/L
Men	: 40 – 129 U/L
Children	: 54 – 369 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

The reagent is linear up to 2000 U/L.

If the concentration is greater than linearity (2000 U/L), dilute the sample with normal saline & repeat the assay. Multiply the result with dilution factor.

2 Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9949 and a regression equation of y =0.9545x.

3. Precision

Intra Run		
	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	96.26	361.66
SD	0.86	1.99
CV(%)	0.89	0.55

Inter Run		
	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	96.13	355.8
SD	3.26	15.65
CV(%)	3.39	4.4

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	103 ± 28	102.08
Control Level 2	390 ± 67	376.58

Sensitivity

Lower detection Limit is 6.0 U/L

Bibliography

1. Clin.Chim.Acta,(1983)339 F-367 F
2. Tietz Textbook of Clinical Chemistry

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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REV. NO.:ADL/IFU/ALPIFCC/25FR/R01 CE ISO 9001:2015 EN ISO 13485:2016