SyRe Accute

AGAPPE

ALKALINE PHOSPHATASE

2 x 50 / 2 x 15 mL
12006002

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

-DGKC – SCE recommended procedure.

-Linear up to 700 U/L

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. Paget's 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 AlkalinePhosphatase (ALP) is based upon the following reaction.

p-nitrophenyl phosphate + H_2O $\xrightarrow{ALP}$ p-nitrophenol+Inorganic phosphate

Kit Components

Reagent/ Component	Product Code 12006002	Description
Alkaline Phosphatase R1	2 x 50 mL	Diethanolamine Buffer (pH 10.2) 125 mmol/L Magnesium Chloride 0.625 mmol/L
Alkaline Phosphatase R2	2 x 15 mL	P-Nitrophenyl phosphate 50 mmol /L

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

Reagent Preparation
Alkaline Phosphatase reagents are ready to use.

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

Open Vial Stability
Once opened the reagents are stable up to 30 days 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 Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum / plasma (Do not use lipemic or 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 reagents

Reagents required but not provided
Multicalibrator (Product Code: 11610001), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Calibration
Agappe Multicalibrator (Product Code: 11610001) is recommended for calibration of the assay.

Quality control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure.

Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should 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

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 700 U/L. If the concentration is greater than linearity (700 U/L), dilute the sample with normal saline and 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= 0.9529 and a regression equation of y = 0.9697x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (U/L)	174.1	665.6	170.6	660.0
SD	6.02	20.31	6.45	25.32
CV(%)	3.45	3.05	3.7	3.8

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	160 ± 55	162.3
Control Level 2	510 ± 95	511.2
Qualicheck Norm	170 ± 18	175.3
Qualicheck Path	400 ± 51	396.2

4. Sensitivity

Lower detection Limit is 1.5 U/L

Bibliography

1. Schlebush, H.*et al*.,Dtsh.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

AGAPPE DIAGNOSTICS LTD.

REV. NO.: ADL/IFU/ALP/40FR/R01

CE ISO 9001:2015
EN ISO 13485:2016

ALKALINE PHOSPHATASE

2 x 50 / 2 x 15 mL
12006002

Accute 40 FR Assay Parameter

Page 1	
Test	ALKALINE PHOSPHATASE
Reaction Mode	Rate
Reference Test ID	**
Test WL	404
Blank WL	NA
Test Read Timing	40-52
Blank Read Timing	NA
Sample	5 µL
R1	200 µL
R2	50 µL
Stirrer	ON
Cal Mode	std
Page 3	
Calibration Mode	Linear
** Not applicable	
# - Input Programme Number only for sample Blanking parameters	