LiquiCHEK™

AGAPPE

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 up to 700 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

Kinetic determination of ALP according to the following reaction

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

ALP = Alkaline Phosphatase

Kit Components

Reagent/ Component	Product code: 11401001	Product code: 11401005	Product code: 11401003	Description
Alkaline Phosphatase (S.L) R1	2 x 8 mL	2 x 24 mL	2 x 40 mL	Diethanolamine buffer (pH10.2) 125 mmol/L Magnesium Chloride - -0.625mmol/L
Alkaline Phosphatase (S.L) R2	2 x 2 mL	2 x 6 mL	2 x 10 mL	P-Nitro phenyl phosphate 50 mmol /L

Risk & safety

Material safety data sheets (MSDS) will be provided on request.

Reagent Preparation

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

The working reagent is stable for 30 days at 2-8^{0}C.

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

Reagent Storage and Stability

The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8^{0}C and protected from light.

Open Vial Stability

Once opened the reagent is stable up to 4 weeksat 2- 8^{0}C, if contamination is avoided

Onboard Calibration Stability

Onboard calibration stability is 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 working reagent to light.

Waste Management

Reagent must be disposed off in accordance with local regulation.

Sample

Serum/Plasma (free of haemolysis).

Interferences

No interference for

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

Materials Provided

Alkaline Phosphatase R1 & Alkaline Phosphatase R2.

Materials required but not provided

- Pipettes& Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameters

Mode of Reaction	Kinetic
Slope of reaction	Increasing
Wavelength	405 nm
Temperature	37^{0}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

Application parameters for various instrument are available. Please contact customer support department for specific information.

Calibration

Agappe multicalibrator is recommended for calibration of this assay on fully auto analyzers.
Use provided factor (2750) for estimation of ALP semi auto analyzers.

Procedure notes

Laboratory Procedure for Semi Auto	
Working reagent	1000 µL
Sample	20 µL
Mix and incubate at 37^{0}C for one minute. Measure the change in absorbance per minute (△ OD/min) during 3 minutes.	

Calculation

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

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 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 finding of patient for interpretation and diagnosis.

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.
'Agappe Hills', Dist. Ernakulam, Kerala, India-683 562.
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REV. NO.: ADL/IFU/ALP/LIQ/R02

CE ISO 9001 : 2015
EN ISO 13485: 2016

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Performance

1. 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.

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)	173.1	660.6
SD	6.04	22.94
CV(%)	3.49	3.47

Inter Run		
	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	163.6	655.0
SD	6.80	27.52
CV(%)	4.15	4.20

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	160 ± 55	164.6
Control Level 2	510 ± 95	509.4
Qualichek Norm	170 ± 18	179.6
Qualichek Path	400 ± 51	392.4

Sensitivity

Lower detection Limit is 1.5 U/L

Bibliography

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

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