ALP – DEA – Instructions for use (IFU)

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

R1: 4 x 50 mL – R2: 4 x 20 mL • REF A-R0200000001

R1: 3 x 18,5 mL – R2: 1 x 18,5 mL • REF R3330000006

IVD CE

INTENDED USE
Quantitative in vitro determination of the concentration of Alkaline phosphatase in human serum and plasma, to be interpreted in clinical contexts. For professional use only.

INTRODUCTION
Alkaline phosphatase (ALP) is an enzyme that reacts optimally to alkaline pH. It is present in blood in numerous forms which come mainly from bone and liver, but also from other tissues such as kidneys, placenta, testicles, and lung tissue, as well as from the presence of tumors. Physiological increases occur during phases of bone growth in children and in pregnancy, which pathological increases are largely associated with hepatobiliary and bone disorders. In terms of hepatobiliary disorders, elevated activity is also observable in infectious hepatitis. The bone disorders that cause an increase in ALP activity are osteoblastic, such as Paget's disease, osteomalacia (rickets), bone metastases and hyper-para-thyroidism.

PRINCIPLE
P – nitrophenylphosphate + H_2O $\xrightarrow{AP}$ phosphate + p-nitrophenol

REAGENTS
A-R0200000001 – R1: 4 x 50 mL – R2: 4 x 20 mL
Reagent 1: n° 4 vials x 42 mL ready to use
Reagent 2: n° 4 vials x 11 mL ready to use
R3330000006 – R1 :3 x 18.5 mL – R2: 1 x 18,5
Reagent 1: n° 3 vials x 14 mL ready to use
Reagent 2: n° 1 vials x 10.5 mL ready to use

Concentration

Reagent A			
	Conc.	**U.M.**	
Diethanolamine pH 9.8	1.2	mol/L	
Magnesium Chloride	0.6	mmol/L	
Reagent B			
p- nitrophenylphosphate	50	mmol/L	

***GHS05_GHS08 Warning: DANGER**
H315 - Causes skin irritation
H318 - Causes serious eye damage
H373 - May cause damage to organs through prolonged or repeated exposure.
P260 - Do not breathe dust/fumes/gases/mist/ vapors /aerosols.
P280 - Wear protective gloves/clothing/Eye/face protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P310 - Contact a POISON CENTER/doctor immediately
P314 Get Medical advice/attention if you feel unwell
P501 - Dispose of the product/container according to current regulations

Precautions
Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to any risk statements relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in EU Regularion1272/2008 EC and subsequent amendments and additions. However, it is recommended to handle the reagents according to the rules of good laboratory practice.

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up to the expiry date reported on the label. A slight variation in the composition of the reagents may occur between batches, but this has no effect on the test results.

Reagent Preparation
The reagents are liquid, ready to use. The solutions must be limpid with no evident precipitate. Pay attention to avoid bacterial contamination during use. The stability of the reagents are 30 days if closed, stored at 2 - 8°C and protect from direct light.

SAMPLE COLLECTION
Type of sample and storage
Use serum or plasma containing heparin or EDTA. The ALP is stable in the serum for 1 week at 2 - 8°C and for at least 3 months at - 20°.

Precautions
All human samples must be handled and disposed of as potentially infectious materials.

Procedure
Quality control
Human control sera with known levels of ALP are commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available as "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems. All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration
For calibration use the "Multicalibrator" code R0300000006. For ISE srl instruments, calibration is recommended every 10 days.

Traceability
The ALP concentration is reported in the package insert supplied with the Calibrator Serum.

Reaction conditions
Wavelenght: 405 nm
Temperature: 37°C

Technique
Bring the reagents to the reaction temperatures.

	U.M.	**Calib serum.**	**Sample**	**White**
Reagent A	µL	1000	1000	1000
Calib serum.	µL	20	-	-
Sample	µL	-	20	-
Water	µL	-	-	20
Mix well and incubate for 1 min. at 37°C and add				
Reagent B	µL	250	250	250

Mix well and after 1 minute of incubation read to 37°C. Read the absorbances of the sample and the calibration serum by subtracting the absorbance of the reagent blank, complete the readings within 3 minutes The reaction volumes can be varied proportionately, the calculation remains unchanged

Results
The concentration of ALP is obtained through the following formula:

$$\frac{\Delta \text{ D.O Sample}}{\Delta \text{ D.O Calibration serum}} \times \text{Calibration serum conc (U/L)} = \text{U/L ALP}$$

Calculation of results obtained against multiplication factor
Δ D.O./min x K-factor* = U/L of ALP
K-factor Reagent B Starter = 3433
K-factor Siero Starter = 2757

Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

ALP – DEA – Instructions for use (IFU)

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

R1: 4 x 50 mL – R2: 4 x 20 mL • REF A-R0200000001

R1: 3 x 18,5 mL – R2: 1 x 18,5 mL • REF R3330000006

IVD CE

NORMAL VALUES

			25°C	30°C	37°C
Adults					
Adults		U/L	< 170	< 211	< 258
Children					
1 – 12 years		U/L	< 480	< 596	< 727
13 – 17 years	Male	U/L	< 617	< 767	< 935
	Female	U/L	< 296	< 367	< 448

Each laboratory should calculate its own normal values on the basis of its local population.

Reagents included in the kit
The reagents are described above.

Materials required but not supplied in the kit
Calibrators and controls.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
Reaction is linear up to 800 U/L.

Specificity
The colour which develops is proportional to the amount of ALP enzymes present in the sample.

Accuracy - Recovery
Accuracy studies have been carried out on normal samples to which APL of known titre was added. The data indicate a recovery of 99%.

Interference
No interference has been observed from Ascorbic Acid for concentrations inferior to 30 mg/dL, for Bilirubin at concentrations inferior to 40 mg/dL, for hemoglobin at concentrations inferior to 150 mg/dL and lipids up to 2000 mg/dL of Triglycerides.

Precision of the method

Within series					
Range	U.M.	Average	S.D.	C.V. (%)	N
Low	U/L	137	1.71	3.53	20
High	U/L	232	2.91	2.48	20
Between series					
Range	U.M.	Average	S.D.	C.V. (%)	N
Low	U/L	137	1.93	5.74	20
High	U/L	232	2.36	4.42	20

Sensitivity
At λ405 nm a concentration of about 3 U/L of ALP in conditions established for this test.

Comparative method
The ALP DGKC method has been compared with a similar (DGKC) method on the market. The results of the comparison were a regression line y = 0.98x -2.21; Correlation Coefficient r = 0.98; number of samples analyzed n = 78.

Disposal of reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

Distributor:
I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 077 4579365; FAX +39 077 4579305
E-mail: info@logotech-ise.com
www.logotech-ise.com

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

Bibliography

1. Diagnostica di Laboratorio Thomas L. clinica. 1a ed. Francoforte: Verlagsgesellschaft TH-Books, 1998. p. 36 - 46.
2. Moss DW, AR Henderson. Enzimologia clinica. In: Burtis CA, Ashwood ER, editori. Tietz Textbook of Chimica Clinica. 3a ed. Philadelphia: Saunders W.B Società; 1999. p. 617-721.
3. Deutsche Gesellschaft für klinische Chemie. Empfehlungen der deutschen Gesellschaft für Klinische Chemie (DGKC). Standardisierung von Methoden zur Bestimmung von Enzymaktivitäten in biologischen Flüssigkeiten.(Recommendation of the German Society of Clinical Chemistry. Standardization of methods for measurement of enzymatic activities in biological fluids.) Z Klin Chem Klin Biochem 1972;10:182-92.
4. Fischbach F, Zawta B. Age-dependent reference limits of several enzymes in plasma at different measuring temperatures. Klin Lab 1992;38:555-61
5. Guder WG, Zawta B et al. La qualità della diagnostica Campioni. 1a ed. Darmstadt: GIT Verlag, 2001; p. 14-5.

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance