ALKALINE PHOSPHATASE SL (IFCC)

Kinetic Method

Liquid Reagent ready to use

REF 12300160 R1 8X20mL
REF 11310040 R2 8X5mL

IVD

PRODUCT CODE: ALP-8D25

Company with Quality System ISO 9001 – ISO 13485Certified by LMS

INTENDED USE

Quantitative determination of alkaline phosphatase (ALP) in serum and plasma in accordance with IFCC recommendations.

PRINCIPLE

The enzyme alkaline phosphatase hydrolizes the p-nitrophenylphosphate (4-NPP) to releasing the p-nitrophenol (4-NP) whose formation rate can be measured spectrophotometrically a 405 nm to quantify the activity of the enzyme present in the sample.

SAMPLE

Serum, plasma with heparin. Do not use other anticoagulants such as EDTA, oxalate and citrate by inhibiting the enzyme. Avoid hemolyzed samples.

Sera kept at room temperature usually show a slight increase in activity, which varies from 1% over a 6-h period to 3-6 % over a 1 to 4 days period. Even in sera stored at refrigerator temperature, activity increases slowly. In frozen sera, activity decreases but slowly recovers after thawing the serum.

KIT COMPONENTS

Reagent (A) ALP Volume = 40/80 ml	Buffer AMP Magnesium ions Zinc ions EDTA	500 mmol/l 2 mmol/l 1 mmol/l 2 mmol/l
Reagent (B) ALP Volume = 10 ml	p-nitrophenylphosfate	16 mmol/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not freeze. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.
Keep bottles closed when not in use.

REAGENTS PREPARATION

Liquid Reagents, bring Reagent to room temperature (15-25°C) before use.

For **use as monoreagent**: add a part of Reagent (B) to 4 parts of Reagent (A).

The working solution (A+B) is stable 1 week at 2-8°C when stored tightly closed, protected from light.

PRECAUTIONS AND WARNINGS

Reagent (A) :
EUH210 Safety data sheet available on request.
Reagent (B) :
EUH210 Safety data sheet available on request.
EUH208 Contains: MIT, May produce an allergic reaction.

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	405 nm
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	increasing kinetic

Use as monoreagent:

pipette:	
Working solution (A+B)	250 µl
sample	5 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. (ΔA/min).

Use as bireagent:

pipette:	
Reagent (A)	200 µl
sample	5 µl
mix and after 1 minute add:	
Reagent (B)	50 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. (ΔA/min).

RESULTS CALCULATIONS

Perform calculation in Units per litre, multiplying the ΔA/min by the factor as it is indicated

ALP (U/L) = ΔA/min x 2757

EXPECTED VALUES

Adults		
Men 20-50 years	53 - 128 U/L	
Women 20-50 years	42 - 98 U/L	
Men > 60 years	56 - 119 U/L	
Women > 60 years	53 - 141 U/L	
Childen	**Female**	**Male**
1 - 30 days	48 - 406 U/L	75 - 316 U/L
30 days - 1 year	124 - 341 U/L	82 - 383 U/L
1 - 3 years	108 - 317 U/L	104 - 345 U/L
4 - 6 years	96 - 297 U/L	93 - 309 U/L
7 - 9 years	69 - 325 U/L	86 - 315 U/L
10 - 12 years	51 - 332 U/L	42 - 362 U/L
13 - 15 years	50 -162 U/L	74 - 390 U/L
16 - 18 years	47 - 119 U/L	52 - 171 U/L

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 15 U/L.

Linearity: the method is linear up to 800 U/L. For higher values, dilute the sample 1:10 and multiply the result by 10.

Precision intra-assay:

	Level 1	Level 2
Mean (U/L)	84.40	222.40
SD	2.41	5.74
CV %	2.86	2.58

Precision inter-assay:

	Level1	Level 2
Mean (U/L)	86.66	210.39
SD	2.66	6.08
CV %	3.07	2.89

Interferences: bilirubin does not interfere up to 40 mg/dl. Triglycerides do not interfere up to 900 mg/dl. Hemoglobin does not interfere up to 400 mg/dl.

Glucose up to 500 mg/dl does not interfere.

Correlation against a reference method:

Y = 1.053x + 2.8975 r = 0.9973

REFERENCES

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2. Vassault, A. et al. Ann. Biol. Clin., 44,686 (1986).
3. Tietz Textbook of Clinical Chemistry, 2th Ed., Burtis-Ashwood (1994).
4. Clinical Laboratory Standards Institute (CLSI). User Verification of Perfomance for Precision and Trueness; Approved Guideline . Second Edition. EP15-A2

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