

ALKALINE PHOSPHATASE SL

Kinetic Method - DGKC
Liquid Reagent ready to use

REF 12200160 R1 8X20mL
REF 11210040 R2 8X5mL

IVD

PRODUCT CODE: ALP-8D25

INTENDED USE

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

PRINCIPLE

The enzyme alkaline phosphatase hydrolyzes the p-nitrophenylphosphate (4-NPP) to releasing the p-nitrophenol (4-NP) whose formation rate can be measured spectrophotometrically at 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 = 80 ml	Buffer DEA Magnesium chloride	1 mol/l 0.5 mmol/l
Reagent (B) ALP Volume = 10 ml	p-nitrophenylphosphate	10 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.

PRECAUTIONS AND WARNINGS

EC Regulation 1272/2008 (CLP):

Reagent (A) :



Danger

H373 May cause damage to organs through prolonged or repeated exposure.

H318 Causes serious eye damage.

H315 Causes skin irritation.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P280 Wear protective gloves / eye protection / face protection.

P310 Immediately call a POISON CENTER or doctor / physician.

P264 Wash with water thoroughly after handling.

Contains: DIETHANOLAMINE

Reagent (B) :

EUH210 Safety data sheet available on request.

EUH208 Contains: MIT, May produce an allergic reaction.

Reagents may contain some non-reactive and preservative components.

Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	405 nm (410 nm)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	increasing kinetic

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



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. ($\Delta A/min$).

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. ($\Delta A/min$).

RESULTS CALCULATIONS

Perform calculation in Units per litre, multiplying the $\Delta A/min$ by the factor as it is indicated:

Activity in U/L : $\Delta A/min \times 2480$ (*)

(*) Factor calculated in our laboratories. We recommend the use of SicuroBio calibrator Acucal (Ref. SB-8327) to verify that this factor is correct for your test system.

EXPECTED VALUES

Adults: 98 – 279 U/L

Children: 250 – 775 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 1600 U/L. For higher values, dilute the sample 1:10 and multiply the result by 10.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	174.6	316.7	596.2
SD	2.547	1.767	9.223
CV %	1.46	0.56	1.55

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	183.5	328.8	591.8
SD	1.958	4.517	6.015
CV %	1.07	1.37	1.02

Interferences: bilirubin does not interfere up to 20 mg/dl. Triglycerides do not interfere up to 1000 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:

$Y = 0.96x - 2.7$ $r = 0.999$

REFERENCES

1. J.Clin. Chem. Clin. Biochem 8 658 (1970).
2. Vassault, A. et al. Ann. Biol. Clin., 44,686 (1986).