ALKALINE PHOSPHATASE (ALP)

Alkaline phosphatase determination in serum and plasma based on recommendations of DGKC

TEST SUMMARY

The alkaline phosphatase catalyses the transformation of p-Nitrophenilphosfate a p-Nitrophenol which formation could be measured spectrophotometrically at 405 nm.

SAMPLES

Serum, plasma (heparinated only).
Stability: 7 days at 2-8°C.

REAGENTS

Reagent A:	Dietanolamine 1M pH 9.8; stabilizers and preservatives.
Reagent B:	p-Nitrophenilphosphate 10 mM; stabilizers and preservatives.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Physiological solution.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GPL) guidelines.

REAGENTS PREPARATION

PROCEDURE SAMPLE STARTER
Add 10 ml of Reagent B to a vial of Reagent A. Stability of the work reagent: ≥ 60 days at 2-8°C away from light sources

PROCEDURE REAGENT STARTER
Use reagents separately. Stability: until expiration date on label away from light sources at 2-8°C.
Stability after first reading : ≥ 60 days.

PROCEDURE (SAMPLE STARTER)

Kind of analysis:	Kinetics (increasing)
Reading time:	1,2,3, minutes
Delay:	60 sec.
Wavelength:	405 nm
Temperature:	37°C
Lightpath	1 cm
Zero:	Distilled water

REAGENTS	CUVETTE
Work Reagent	1 ml
Preincubate at 37 °C for at least 5 minutes	
Samples	20 µl

PROCEDURE (REAGENT STARTER)

Kind of analysis:	Kinetics (increasing)
Reading time:	1,2,3, minutes
Wavelength:	405 nm
Delay:	60 sec.
Temperature:	37°C
Lightpath	1 cm
Zero:	Distilled water

REAGENTS	CUVETTE
Reagent A Sample	1 ml 25 µl
Preincubate at 37 °C for at least 5 minutes	
Reagent B	250 µl

CALCULATION

Activity in U/l: ΔA/min x 2757

Activity in µkat/l: U/l x 0.0167

EXPECTED VALUES

Men	<270 U/l	(<4.50 µkat/l)
Women	<240 U/l	(<4.00 µkat/l)

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

NOTES

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH **10 x 5 ml**
Control Sera normal values

QP 0050 CH **10 x 5 ml**
Control Sera pathological values

TEST PERFORMANCE

Precision

Intra-assay (n = 10)	Mean (U/l)	SD (U/l)	CV%
Sample 1	175.70	0.95	0.50
Sample 2	426.70	2.41	0.60

Inter-assay (n = 20)	Mean (U/l)	SD (U/l)	CV%
Sample 1	167.26	3.99	2.40
Sample 2	408.28	8.61	2.10

Sensibility/limit of detection
Method is able to discriminate up to 1 U/l.

Linearity
The method is linear up to 2800 U/l.
If ΔA/min exceeded of 0.500, is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the results by 10.

Methods comparison
A comparison with a commercial available product gave the following results in a comparison on 112 samples:

ALP LTA = x
ALP competitor = y
n = 112

y = 0,96x - 2,17 U/l r = 0,999

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 400 mg/dl
bilirubin	≤ 27 mg/dl
lipids	≤ 1000 mg/dl

WASTE DISPOSAL

Product is intended for professional laboratories.
Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CC01600	**(200 TESTS)**	
Reagent A	4 x 40 ml	(liquid)
Reagent B	1 x 40 ml	(liquid)

REFERENCES

J. Clin. Chem.Clin.Biochem 8 (1970) 658; 10 (1972) 182.
Tietz Texbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

MANUFACTURER

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SYMBOLS

IVD	Only for IVD use
LOT	Lot of manufacturing
REF	Code number
	Storage temperature interval
	Expiration date (year, month)
	Warning, read enclosed documents
	Read the directions
	Biological risk

Mod. 01.06 (ver. 4.3 - 04/03/2006)

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