

ALKALINE PHOSPHATASE (ALP) IFCC

Diagnostic reagent for determination of Alkaline Phosphatase concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2020	5 x 100 mL	DM2020	840 Tests	BY2020	7670 Tests	K2021	3636 Tests
A2021	5 x 50 mL	R2020	2885 Tests	BY2021	5114 Tests	M2020	2512 Tests
A2022	5 x 25 mL	R2021	962 Tests	N2020	800 Tests	M2021	1675 Tests
T2020	3474 Tests	S2020	3077 Tests	N2021	400 Tests	L2020	3750 Tests
T2021	1975 Tests	S2021	1477 Tests	K2020	5455 Tests	L2021	2000 Tests

INTENDED USE

This test is applied for the quantitative determination of ALP (Alkaline Phosphatase) in human serum and heparinate plasma.

TEST PRINCIPLE

The enzyme alkaline phosphatase (EC 3.1.3.1, orthophosphoric-monoester phosphohydrolase) hydrolyzes the 4- NPP to release 4-nitrophenol, under alkaline conditions.

The 4-nitrophenol formed is detected spectrophotometrically at 405 nm to give a measurement of alkaline phosphatase activity in the sample.

The present method has been made according to IFCC.

TEST PARAMETERS

Method	: Colorimetric, Kinetic, Increasing Reaction IFCC
Wavelength	: 405 nm
Temperature	: 37°C
Sample	: Serum, heparin Plasma
Linearity	: 10 U/L - 3000 U/L

REAGENT COMPOSITION

Composition	Final concentration
2-amino-2-methyl-1-propanol buffer	≤ 0.35 M
pH 10.40 (30°C),	
Magnesium acetate	≤ 2 mM
Zinc sulfate	≤ 1 mM
HEDTA	≤ 2 mM
4-NPP	≤ 16 mM.

REAGENT PREPARATION

Sample Start:

Mix 4 parts of Reagent 1 (Buffer) with 1 part of Reagent 2 (Starter). For example: 4ml Reagent 1 and 1ml Reagent 2. Avoid foaming.

Stability of working reagent: 30 days at 2-8°C, away from light sources.

Working reagents are stable at 2-8°C in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8 C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum and heparinate plasma are collected by standard procedures.

Sera kept at room temperatures usually show a slight but real increase in activity, which varies from 1% over a 6-h period to 3 to 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.

A similar enhancement of activity, but of greater magnitude, occurs with reconstituted lyophilized preparations, such as those available as control sera or calibrators. In reconstituted material, the

increases with storage at 4 and 20°C are about 10 and 30%, respectively. Enhancement of activity continues for several days, but at a decreasing rate. The cause of this phenomenon is not known but maybe attributed to renaturation of partially denatured enzyme or to dissociation, on warming, of a phosphate-lipoprotein complex or a multimer of the enzyme that was formed in the freeze-drying process.

ALP in serum is stable for 7 days at 20 - 25°C, 7 days at 2-8°C and 2 month at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

For Sample Start:

$\Delta A/\text{min} \times 2757 = \text{U/L Alkaline phosphatase in sample}$

Unit Conversion

$\text{U/L} = 10 \times \text{U/dL}$

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Men : 35 - 104 U/L (0.58 - 1.74 $\mu\text{kat/L}$)

Women: 40 - 129 U/L (0.67 - 2.15 $\mu\text{kat/L}$)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with alkaline phosphatase values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The use of a Alkaline Phosphatase Calibrator (for automated Systems) is optional. We recommend ARCAL Calibrator ("Arcal Auto")

Cat. No. A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 10 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 10 U/L

High Linearity: The method is linear up to 3000 U/L.

If a $\Delta A/\text{min}$ of 0.500 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (Intra-assay)

Mean (U/L)	SD (U/L)	CV%	n
84.40	2.41	2.86	10
222.40	5.74	2.58	10

Reproducibility (run to run) (Inter-assay)

Mean (U/L)	SD (U/L)	CV%	n
86.66	2.66	3.07	20
210.39	6.08	2.89	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 5.2 U/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Methods comparison: A comparison between Archem and a commercially available product gave the following results:

ALP Archem = x
 ALP competitor = y
 n = 150
 $y = 1.03x - 2.57 \text{ U/L}$
 $r^2 = 0.998$

Interferences: No interference was observed by the presence of:

Hemoglobin $\leq 400 \text{ mg/dL}$
 Bilirubin $\leq 40 \text{ mg/dL}$
 Lipids $\leq 900 \text{ mg/dL}$

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

R36/38 : Irritating to eyes and skin.

S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.

S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.

S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.




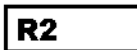








ABBREVIATIONS

ALP	: Alkaline Phosphatase
CLSI	: Clinical and Laboratory Standards Institute
CV%	: Coefficient of Variation Percentage
EP	: Evaluation Protocols
GLP	: Good Laboratory Practice
IU	: International Unit
mA	: milliabsorbance
mL	: milliliter
NCCLS	: National Committee for Clinical Laboratory Standards
QC	: Quality Control

REFERENCES

1. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press (1990).
2. HAUSAMEN T.U., HELGER R., RICK W., GROSS W., Clin. Chim. Acta 15:241 (1974)
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4. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
5. Clinical Chemistry: Principles and Technics, Ed. J. HENRY HARPER and ROW N.Y. (1974)
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SYMBOLS

	Only for invitro diagnostic use
	Lot of manufacturing
	Reagent 1
	Reagent 2
	Concentration
	Reagent Ingredients
	Reference Number (Catalog No)
	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk



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