ALP

En

REF T2022 3348 Tests
REF T2023 1720 Tests

FOR USE WITH
ARCHITECT

Diagnostic reagent for determination of Alkaline Phosphatase (ALP) concentration.
Liquid. Dual Reagents *(Ratio: R1/R2: 4/1)*. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.
T2022 / T2023 Ref Number Products are Produced Specifically for Abbott Architect Chemistry Analyzer Series.

Changes made in the instructions for use are marked as grey.

INTENDED USE

This test is applied for the quantitative determination of ALP in human serum and plasma.

TEST SUMMARY AND PROCEDURE [1, 2, 3]

Alkaline Phosphatase (ALP; E.C.3.I.3.1.) is a membrane bound glycoprotein which catalyzes the hydrolysis of phosphate monoesters at basic pH value and which is present everywhere. The enzyme produced by the liver, bowel and placenta is excreted from the body. The enzyme levels increase in pathologies such as bone tumors, liver damage, obstruction of the biliary tract.

The enzyme alkaline phosphatase hydrolizes the 4- NPP to release 4-nitrophenol, under alkaline conditions. The 4-nitrophenol form 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 (International Federation of Clinical Chemistry and Laboratory Medicine).

TEST PARAMETERS

Method	: Colorimetric, Kinetic, Increasing Reaction IFCC
Wavelength	: 400 - 420 nm
Linearity	: 1000 U/L

REAGENT COMPONENTS

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

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE [4]

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 10 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

Serum and plasma are collected according to the standard procedures.

ALP in serum is stable for:
7 days at +20/+25°C,
7 days at +2/+8°C,
2 months at -20°C.

Unit Conversion:
U/L = 10 x U/dL

REFERENCE INTERVAL (NORMAL VALUES) [5]

Men	: 40 - 129 U/L
Women	: 35 - 104 U/L

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

Reference interval has been verified by using Clinical and Laboratory Standards Institute (CLSI) EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

Arcon N (Level I Control) Lyophilized
Ref.No: A3910

Arcon P (Level II Control) Lyophilized
Ref.No: A3920

The assay requires the use of a Multiconstituent Calibrator We recommend:

Multiconstituent Calibrator
Ref.No: A39053

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 10 days.

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

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

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): Limit of detection of the test is 5.2 U/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) %≤ 20]**:**[6] 10 U/L

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 1000 U/L.

For values above high linearity, dilute sample with %0.9 saline, repeat the test and multiply the result by the dilution factor.

Precision Studies:[7]

Repeatability (Within Run):

Mean Concentration	SD*	CV%	n
78,62 U/L	1,35	1,71	40
205,36 U/L	0,89	0,43	40

Reproducibility (Day-to-Day Run):

Mean Concentration	SD	CV%	n
75,07 U/L	3,21	4,27	84
205,29 U/L	7,20	3,50	84

*SD: Standard Deviation

*CV: Variation Coefficient
±10% CV% deviations between devices can be observed

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[8, 9]
Correlation with a comparative method is: r= 0.998
According to Passing-Bablok Fit:
Slope: 1.03
Intercept: -2.57

Interference:[3, 10]
No significant interference was observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given in the table.

Interfering Substance and Concentration	ALP Target (U/L)	N	Observed Recovery %
Hemoglobin 990 mg/dL	85	85	107
Bilirubin 58.5 mg/dL	165	165	98
Lipemia 825 mg/dL	89	89	94

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

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

WARNINGS AND PRECAUTIONS

IVD**:** For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032	:Releases a very toxic gas if contacts with acid.
H317	:May cause allergic skin reaction.

Precaution

P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

REFERENCES

1. Sharma U, Pal D, Prasad R. Alkaline phosphatase: an overview. Indian J Clin Biochem. 2014 Jul;29(3):269-78. doi: 10.1007/s12291-013-0408-y. Epub 2013 Nov 26. PMID: 24966474; PMCID: PMC4062654.
2. Appendix E: Stem Cell Markers . In Stem Cell Information [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009 [cited Monday, January 02, 2012]
3. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
4. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
5. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
6. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
7. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
8. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26.783-79.
9. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline.CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
10. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline.CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition.
11. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press (1990).
12. HAUSAMEN T.U., HELGER R., RICK W., GROSS W., Clin. Chim. Acta 15:241 (1974)
13. Clin. Chim. Acta, (1983) 339F - 367F
14. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
15. Clinical Chemistry: Principles and Technics, Ed. J. HENRY HARPER and ROW N.Y. (1974)
16. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practice
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limitation
	Consult Instructions for Use
	Caution
	Number of Tests