BioMajesty®

Alkaline phosphatase FS* IFCC mod. 37°C

Order Information

Cat. No.
1 0441 99 10 962

Kit size
Σ 1320 (R1: 6 x 220, R2: 6 x 220)

Intended Use

Diagnostic reagent for quantitative in vitro determination of alkaline phosphatase activity in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Alkaline phosphatase (AP) is a cell membrane bound enzyme, expressed by all tissues [1]. AP, with its cofactors zinc and magnesium, catalyzes hydrolysis of organic phosphate esters in the extracellular space [2]. AP exists in blood in numerous distinct forms which originate mainly from bone and liver, but also from other tissues like kidney, placenta, testes, thymus, lung and tumors. An increase in AP activity can be physiologically induced, e.g. during the 2nd trimester of pregnancy and in childhood during growth. Pathologic conditions, that lead to increased AP activities, are hepatobiliary diseases, diseases of skeletal system, malignant tumors and systemic diseases without primary liver and bone involvement. Decreased AP activities in serum are very rare and are found e.g. in hereditary hypophosphemia, Wilson's disease and in corticoid induced osteoporosis [1].

Method

Kinetic photometric test, according to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) [modif.] [3].

$$\text{p-Nitrophenylphosphate} + H_2O \xrightarrow{\text{AP}} \text{Phosphate} + \text{p-Nitrophenol}$$

One unit of alkaline phosphatase is the amount of enzyme that will convert 1.0 µmol of p-nitrophenylphosphate in presence of H_2O to phosphate and p-nitrophenol per minute at the enzyme specific conditions.

Reagents

Components and Concentrations

R1:	2-Amino-2-methyl-1-propanol	pH 10.4	1.1 mol/L
	Magnesium acetate		2 mmol/L
	Zinc sulphate		0.5 mmol/L
	HEDTA		2.5 mmol/L
R2:	p-Nitrophenylphosphate		80 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 12 months until expiry date.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. During the reaction, p-nitrophenol is produced which is poisonous when inhaled, swallowed or absorbed through skin. If the reaction mixture comes in contact with skin or mucous membranes wash copiously with water!
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Do not use hemolytic samples.

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [5]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
2 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. This method is traceable to the molar extinction coefficient. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 1400 U/L, linearity is given within ± 5%.
In case of higher activities, re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.6 U/L
Onboard stability	6 days
Calibration stability	6 days

Interference by	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	30 mg/dL	99.6
Bilirubin (conjugated)	60 mg/dL	97.6
Bilirubin (unconjugated)	36 mg/dL	97.3
Hemolysis	150 mg/dL	99.9
Lipemia (triglycerides)	2000 mg/dL	99.0

For further information on interfering substances, refer to the literature. [6-8]

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Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	86.4	197	277
CV [%]	0.656	0.716	0.533
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	29.7	139	305
CV [%]	3.10	1.49	1.70

Method comparison (n=100)	
Test x	Competitor Alkaline phosphatase (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Alkaline phosphatase FS (BioMajesty® JCA-BM6010/C)
Slope	1.03
Intercept	3.96 U/L
Coefficient of correlation	0.999

** lowest measurable activity which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor
AP [U/L] x 0.0167 = AP [µkat/L]

Reference Range [1]

	Female		Male	
Children	**[U/L]**	**[µkat/L]**	**[U/L]**	**[µkat/L]**
0 – 1 year	89 – 370	1.49 – 6.3	89 – 370	1.49 – 6.3
1 – 3 year(s)	91 – 334	1.52 – 5.6	91 – 334	1.52 – 5.6
4 – 6 years	97 – 316	1.61 – 5.3	97 – 316	1.61 – 5.3
7 – 11 years	120 – 340	2.00 – 5.7	110 – 316	1.83 – 5.3
13 – 17 years	49 – 328	0.82 – 5.5	75 – 363	1.25 – 6.1
Adults	33 – 98	0.55 – 1.64	43 – 115	0.72 – 1.92

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 Jun 10]. Available from: https://www.clinical-laboratory-diagnostics.com/
2. Lowe D, Sanvictores T, Zubair M, et al. Alkaline Phosphatase. [Updated 2023 Oct 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. [cited 2023 Dec 29]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK459201/
3. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 9: Reference procedure for the measurement of catalytic concentration of alkaline phosphatase; Clin Chem Lab Med 2011;49(9).
4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
5. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 32-3.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products [Internet]. AACC Press and John Wiley and Sons, Inc; 2020 [cited 2024 June]. Available from: https://clinfx.wiley.com/ aaccweb/aacc/
8. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

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Chemistry code 10 044

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.5
Sample vol (U)	1.5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	AP
Digits	2
M-wave L.	410
S-wave.L	694
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.5	1.5
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	25
M-DET.P.n	42
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.7
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999