


Alkaline phosphatase FS*

IFCC mod. 37°C

Order Information

Cat. No.	Kit size	Instrument	
1 0441 99 10 972	R1 3 x 11.8 mL	BX-3010	270 (3 x 90)
		BX-4000	186 (3 x 62)
	R2 3 x 5.1 mL	BX-3010	270 (3 x 90)
		BX-4000	186 (3 x 62)

Intended Use

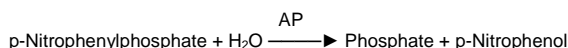
Diagnostic reagent for quantitative in vitro determination of alkaline phosphatase (AP) in serum or plasma on Sysmex BX-Series.

Summary

Alkaline phosphatase (AP), a hydrolytic enzyme acting optimally at alkaline pH, exists in blood in numerous distinct forms which originate mainly from bone and liver, but also from other tissues as kidney, placenta, testes, thymus, lung and tumors. Physiological increases are found during bone growth in childhood and in pregnancy, while pathological increases are largely associated with hepatobiliary and bone diseases. In hepatobiliary disease they indicate obstruction of the bile ducts as in cholestasis caused by gall stones, tumors or inflammation. Elevated activities are also observed in infectious hepatitis. In bone diseases elevated AP activities originate from increased osteoblastic activity as in Paget's disease, osteomalacia (rickets), bone metastases and hyperparathyroidism. [1,2]

Method

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



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

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them from light.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- 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!
- In very rare cases, samples of patients with gammopathy might give falsified results [4].
- Please refer to the safety data sheets 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.
- For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Do not use hemolytic samples.

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. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 1400 U/L (23.3 µkat/L). In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.5 U/L (0.008 µkat/L)
Onboard stability	9 days
Calibration stability	9 days

Interfering substance	Interferences ≤ 10% up to	Analyte concentration
Ascorbic acid	30 mg/dL	100 U/L (1.66 µkat/L)
Bilirubin (conjugated)	60 mg/dL	97.8 U/L (1.63 µkat/L)
Bilirubin (unconjugated)	36 mg/dL	97.5 U/L (1.63 µkat/L)
Hemoglobin	100 mg/dL	59.5 U/L (0.992 µkat/L)
	250 mg/dL	122 U/L (2.04 µkat/L)
Lipemia (triglycerides)	2000 mg/dL	55.1 U/L (0.919 µkat/L)
	2000 mg/dL	125 U/L (2.08 µkat/L)

For further information on interfering substances refer to Young DS [6].

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	60.1	126	155
Mean [µkat/L]	1.00	2.10	2.58
CV [%]	0.898	0.382	0.479
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	59.5	126	173
Mean [µkat/L]	0.992	2.10	2.88
CV [%]	1.45	1.10	0.741

Method comparison (n=109)	
Test x	Alkaline phosphatase FS (BioMajesty® 6010C)
Test y	Alkaline phosphatase FS (BX-4000)
Slope	0.990
Intercept	-1.89 U/L (-0.032 µkat/L)
Coefficient of correlation	0.9999

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

Reference Range

Adults [7]		
Women	35 – 104 [U/L]	0.58 – 1.74 µkat/L
Men	40 – 129 [U/L]	0.67 – 2.15 µkat/L

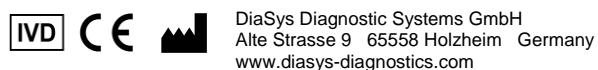
Adults [8]		
Women	35 – 105 [U/L]	0.58 – 1.75 µkat/L
Men	40 – 130 [U/L]	0.67 – 2.17 µkat/L

Children [9]				
	Female [U/L]	Male [U/L]	Female [µkat/L]	Male [µkat/L]
1 – 30 day(s)	48 – 406	75 – 316	0.80 – 6.77	1.25 – 5.27
1 month – 1 year	124 – 341	82 – 383	2.07 – 5.68	1.37 – 6.38
1 – 3 year(s)	108 – 317	104 – 345	1.80 – 5.28	1.73 – 5.75
4 – 6 years	96 – 297	93 – 309	1.60 – 4.95	1.55 – 5.15
7 – 9 years	69 – 325	86 – 315	1.15 – 5.42	1.43 – 5.25
10 – 12 years	51 – 332	42 – 362	0.85 – 5.53	0.70 – 6.03
13 – 15 years	50 – 162	74 – 390	0.83 – 2.70	1.23 – 6.50
16 – 18 years	47 – 119	52 – 171	0.78 – 1.98	0.87 – 2.85

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. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 36-46.
2. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617-721.
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, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
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. Abicht K et al. Multicenter evaluation of new GGT and ALP reagents with new reference standardization and determination of 37 °C reference intervals. Clin Chem Lab Med 2001; 39 (Suppl.): S 346 [abstract].
8. Thomas L, Müller M, Schumann G, Weidemann G et al. Consensus of DGKL and VDGH for interim reference intervals on enzymes in serum. J Lab Med 2005;29:301-308.
9. Soldin JS, Brugnara C., Wong CE. In: MJ Hicks, editor. Pediatric reference intervals. 6th ed. Washington: AACC Press, 2007. p. 11.



* Fluid Stable

Chemistry Parameters 1		Sysmex BX-3010 Chemistry Analyzer Analytical Parameters					
Method No.	*	Method Name	ALP	Reagent Name	Reagent (µL)	Water (µL)	
Print Name	ALP	MethodColor		R1	ALP	100	
Sample Type	Serum			R2	ALP	25	
Unit	U/L			Diluent	Disable		
Assay Type	Rate			Sample Ppt. Wash	Disable		
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle	
		1	30 - 46				
		2	Disable -				
Wave Length	Prim. 415	Sec. 700		Normal Range			
				No.	Normal Range Name	Min	Max
				1	Male-G1	*	*
				2	Male-G2	*	*
				3	Male-G3	*	*
				4	Female-G1	*	*
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range			
	Low 0.0	Normal 1.9	High 0.0	(Conc)	1	1400	
<input type="checkbox"/> Diluent	0.0 <	1.9 <	0.0	(mAbs/10)	*	*	
	Rerun (High/Prozone)			Previous Result Comparison (%)	*	*	%
<input type="checkbox"/> Diluent	0.0 <	1.9 <	0.0	Abnormal Range	(Conc)	*	*
	Rerun (Low)			Panic Range	(Conc)	*	*
<input type="checkbox"/> Diluent	0.0 <	1.9 <	0.0	Decimal Point	0	Profile SI	Disable

*Entered by user

Chemistry Parameters 2		Sysmex BX-3010 Chemistry Analyzer Analytical Parameters	
Method No.	*	Method Name	ALP
		Sample	Serum
Limit Checks		Blank measurement	
<input checked="" type="checkbox"/> Duplicate Limit	50	mAbs/10	Blank measurement:
<input checked="" type="checkbox"/> Sensitivity Limit	400	mAbs/10	Disable reagent blank and C1 blank
<input checked="" type="checkbox"/> Linearity Limit	10	%	Measurement of Reagent Blank during Run:
	370	(mAbs/10)/min	None
<input type="checkbox"/> Prozone Limit	Higher	%	Reagent blank measurement at calibration:
			Reagent blank (No sample)
SL1-S		SL1-F	The number of measurement:
			Duplicate
SL2-S		SL2-F	Reagent blank limit checks:
			<input checked="" type="checkbox"/> Duplicate Limit
Sensitivity		mAbs/10	10
<input checked="" type="checkbox"/> Absorbance Limit			Instrument Factor
Abs. in reaction	Increase		a 1.00
Limit	25000	mAbs/10	b 0.00

Calibration Registration

**Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters**

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.
(R1) Last

(R2)

The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

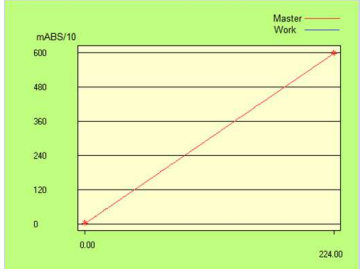
Absorbance mAbs/10

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Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters		
Method	*	Name	ALP	Reagent Name	Reagent (μL)	Water (μL)
Print Name	ALP			R1	ALP	150
Sample	Serum			R2	ALP	38
Unit	U/L			<input checked="" type="checkbox"/> Enable		
Assay Type	Rate			Diluent	<input type="checkbox"/> Enable	
Measuring points	Start	End	Decimal Points	0		
	1	44 - 68				
<input type="checkbox"/> Enable	2					
Wave Length	Prim.	415	Sec	<input type="checkbox"/> Disable	700	
				Normal Range		
				No.	Normal Range Name	Min
				1	Male-G1	*
				2	Male-G2	*
				3	Male-G3	*
				4	Female-G1	*
				Technical Range		
<input type="checkbox"/> Dilution	Normal Sampling	Sample (μL)	Diluent (μL)	(Conc)	1	1400
<input type="checkbox"/> Rerun (High/Prozone)				(mAbs/10)		
<input type="checkbox"/> Dilution	2.9					
<input type="checkbox"/> Rerun (Low)						
<input type="checkbox"/> Dilution	2.9					
				SPT Wash	<input type="checkbox"/> Enable	Reagent Name
				Stirring Speed	R1	Middle
					R2	Middle

*Entered by user

Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters		
Method No.	*	Name	ALP	Sample	Serum	
Limit Checks				Blank measurement		
<input checked="" type="checkbox"/> Duplicate Limit		50	mAbs/10	Blank measurement:		
<input checked="" type="checkbox"/> Sensitivity Limit		400	mAbs/10	Disable reagent blank and S1 blank		
<input checked="" type="checkbox"/> Linearity Limit		10	%	370	(mAbs/10)/min	
<input type="checkbox"/> Prozone Limit			%	Upper		
	SL1-S		-	SL1-F		
	SL2-S		-	SL2-F		
	Sensitivity		mAbs/10	Measurement of Reagent Blank during Run:		
<input checked="" type="checkbox"/> Absorbance Limit				None		
	Reaction	Increase		Reagent blank measurement at calibration:		
	Limit	25000	mAbs/10	Reagent blank (No sample)		
				The number of measurement:		
				Duplicate		
				Reagent blank limit checks:		
				<input checked="" type="checkbox"/> Duplicate Limit	10	mAbs/10
				Instrument Factor		
				a	1.00	b
						0.00

Registration Calibration		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																															
Method <input type="text" value="*"/> Name <input type="text" value="ALP"/>	R Lot No. R1 <input type="text" value="*"/> Last <input type="text"/>																																																
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Auto <input type="text" value="Change Lot"/> <input type="text" value="Full Calibration"/>																																																	
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<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">Conc.</th> <th style="width: 15%;">WORK</th> <th style="width: 15%;">MASTER</th> <th style="width: 15%;">Lot No. (S)</th> <th style="width: 10%;"><input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr> <td>S1</td> <td>0</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S3</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S4</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S5</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S6</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S7</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Conc.	WORK	MASTER	Lot No. (S)	<input type="checkbox"/> All	S1	0	Automatic entry	Automatic entry			S2	*	Automatic entry	Automatic entry			S3	*					S4	*					S5	*					S6	*					S7	*					Reagent blank <input type="text"/> mAbs/10 Last <input type="text"/>
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