

Alkaline phosphatase FS* (IFCC mod. 37°C)

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

Order information

Cat. No.	Kit size	Number of tests
1 0441 99 10 972	R1 3 x 11.8 mL	BX-3010 3 x 90 tests BX-4000 3 x 62 tests
	R2 3 x 5.1 mL	BX-3010 3 x 90 tests BX-4000 3 x 62 tests

Method

Kinetic photometric test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [mod.]

Principle

p-Nitrophenylphosphate + H₂O $\xrightarrow{\text{AP}}$ Phosphate + p-Nitrophenol

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 Instructions and Reagent Stability

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

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 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 [9].
- 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

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum or heparin plasma
Do not use hemolytic samples!

Stability [1]:

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

For calibration the DiaSys TruCal U calibrator is recommended. This method is traceable to the molar extinction coefficient. For internal quality control DiaSys TruLab N and P controls should be assayed. 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 (23.3 µkat/L) AP (in case of higher activities re-measure samples after manual dilution with NaCl (9 g/L) or use rerun function)	
Limit of detection**	0.5 U/L (0.008 µkat/L) AP
On-board stability	9 days
Calibration stability	9 days

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

For further information on interfering substances refer to Young DS [2].

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
Coefficient of variation [%]	0.898	0.382	0.479
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	59.5	126	173
Mean [µkat/L]	0.992	2.10	2.88
Coefficient of variation [%]	1.45	1.10	0.741

Method comparison (n=109)	
Test x	Alkaline phosphatase FS IFCC (BioMajesty 6010C)
Test y	Alkaline phosphatase FS IFCC (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

Conversion factor

AP [U/L] x 0.0167 = AP [µkat/L]

Reference Range

Adults [3]

Women	35 – 104 [U/L]	0.58 – 1.74 μ kat/L
Men	40 – 129 [U/L]	0.67 – 2.15 μ kat/L

Adults [4]

Women	35 – 105 [U/L]	0.58 – 1.75 μ kat/L
Men	40 – 130 [U/L]	0.67 – 2.17 μ kat/L

Children [5]

		Female	Male
1 – 30 day(s)	[U/L]	48 – 406	75 – 316
1 month – 1 year	[U/L]	124 – 341	82 – 383
1 – 3 year(s)	[U/L]	108 – 317	104 – 345
4 – 6 years	[U/L]	96 – 297	93 – 309
7 – 9 years	[U/L]	69 – 325	86 – 315
10 – 12 years	[U/L]	51 – 332	42 – 362
13 – 15 years	[U/L]	50 – 162	74 – 390
16 – 18 years	[U/L]	47 – 119	52 – 171

		Female	Male
1 – 30 day(s)	[μ kat/L]	0.80 – 6.77	1.25 – 5.27
1 month – 1 year	[μ kat/L]	2.07 – 5.68	1.37 – 6.38
1 – 3 year(s)	[μ kat/L]	1.80 – 5.28	1.73 – 5.75
4 – 6 years	[μ kat/L]	1.60 – 4.95	1.55 – 5.15
7 – 9 years	[μ kat/L]	1.15 – 5.42	1.43 – 5.25
10 – 12 years	[μ kat/L]	0.85 – 5.53	0.70 – 6.03
13 – 15 years	[μ kat/L]	0.83 – 2.70	1.23 – 6.50
16 – 18 years	[μ kat/L]	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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
2. 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.
3. 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].
4. 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.
5. Soldin JS, Brugnara C., Wong CE. In: MJ Hicks, editor. Pediatric reference intervals. 6th ed. Washington: AACCPress, 2007. p. 11.
6. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 36-46.
7. 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).
8. 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.
9. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

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	*	*
	Rerun (Low)			Panic Range	*	*
<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:	Disable reagent blank and C1 blank	
<input checked="" type="checkbox"/> Sensitivity Limit	400	mAbs/10		Measurement of Reagent Blank during Run:	None	
<input checked="" type="checkbox"/> Linearity Limit	10	%		Reagent blank measurement at calibration:	Reagent blank (No sample)	
	370	(mAbs/10)/min		The number of measurement:	Duplicate	
<input type="checkbox"/> Prozone Limit	Higher	%		Reagent blank limit checks:		
				<input checked="" type="checkbox"/> Duplicate Limit	10	mAbs/10
	SL1-S	-	SL1-F	Instrument Factor		
				a	1.00	b 0.00
	SL2-S	-	SL2-F			
	Sensitivity		mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit						
	Abs. in reaction	Increase				
	Limit	25000	mAbs/10			

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

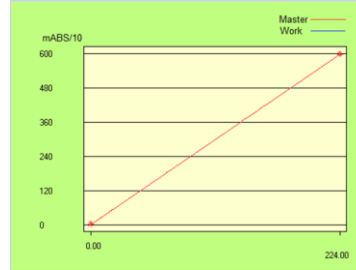
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

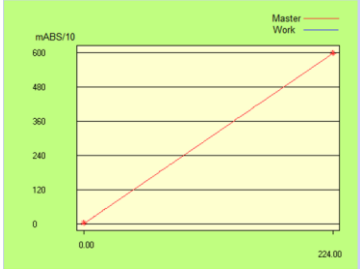
Absorbance mAbs/10

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="ALP"/>																						
Print Name	<input type="text" value="ALP"/>	R1	<input type="text" value="ALP"/>	<input type="text" value="150"/>	<input type="text"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="ALP"/>	<input type="text" value="38"/>																				
Unit	<input type="text" value="U/L"/>																								
Assay Type	<input type="text" value="Rate"/>	Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>																				
Measuring points		Start	End	Decimal Points	<input type="text" value="0"/>																				
	<input type="checkbox"/> Enable	1	<input type="text" value="44"/> - <input type="text" value="68"/>																						
		2	<input type="text"/> - <input type="text"/>																						
Wave Length	Prim. <input type="text" value="415"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>																					
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>						No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
<input type="checkbox"/> Normal Dilution <input type="text" value="2.9"/>		Sampling	Sample (μL)	Diluent (μL)	Technical Range																				
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<input type="checkbox"/> Dilution <input type="text" value="2.9"/>					(mAbs/10) <input type="text"/> - <input type="text"/>																				
<input type="checkbox"/> Rerun (Low)																									
<input type="checkbox"/> Dilution <input type="text" value="2.9"/>																									
			SPT Wash	<input type="checkbox"/> Enable	Reagent Name <input type="text"/>																				
			Stirring Speed	R1 <input type="text" value="Middle"/>	R2 <input type="text" value="Middle"/>																				

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters					
Method No.	* <input type="text"/>	Name	<input type="text" value="ALP"/>	Sample	<input type="text" value="Serum"/>		
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