


## Alkaline phosphatase FS\* IFCC mod. 37°C

### Order Information

#### Cat. No.

1 0441 99 10 920

#### Kit size

 800 (4 x 200)

### Intended Use

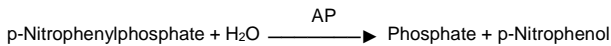
Diagnostic reagent for quantitative in vitro determination of alkaline phosphatase activity in human serum or heparin plasma on automated respons<sup>®</sup>910.

### 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].



One unit of alkaline phosphatase is the amount of enzyme that will convert 1.0 μmol of p-nitrophenylphosphate in presence of H<sub>2</sub>O to phosphate and p-nitrophenol per minute at the enzyme specific conditions.

### Reagents

#### Components and Concentrations

<b>R1:</b>	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
<b>R2:</b>	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

- 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].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.
- 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 from 2.64 U/L 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**	2.64 U/L
Limit of quantitation**	2.64 U/L
Onboard stability	7 days
Calibration stability	7 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Bilirubin (conjugated)	80 mg/dL	95.2
	80 mg/dL	182
Bilirubin (unconjugated)	70 mg/dL	94.9
	70 mg/dL	188
Hemolysis	100 mg/dL	74.2
	100 mg/dL	310
Lipemia (triglycerides)	2200 mg/dL	98.6
	2200 mg/dL	202

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

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	76.6	122	229
CV [%]	1.62	1.44	1.81
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	73.7	127	213
CV [%]	4.04	4.83	3.13

Method comparison (n=117)	
Test x	DiaSys Alkaline phosphatase FS (Hitachi 911)
Test y	DiaSys Alkaline phosphatase FS (respons <sup>®</sup> 910)
Slope	1.05
Intercept	-4.67 U/L
Coefficient of correlation	0.999

\*\* according to CLSI document EP17-A, Vol. 24, No. 34

### Conversion Factor

AP [U/L] x 0.0167 = AP [μkat/L]

### Reference Range [1]

	Female		Male	
	[U/L]	[μkat/L]	[U/L]	[μkat/L]
<b>Children</b>				
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
<b>Adults</b>	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.



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\* Fluid Stable

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### 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	AP
Shortcut:	
Reagent barcode reference:	014
Host reference:	014

Technic	
Type:	Linear kinetic
First reagent:[μL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	6:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance limit	1.4000
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μL]	0 (no hemolysis)
Cleaner	
Sample [μL]	0
Technical limits	
Concentration technical limits-Lower	2.6400
Concentration technical limits-Upper	1400.0000
SERUM	
Normal volume [μL]	3.0
Normal dilution (factor)	1
Below normal volume [μL]	
Below normal dilution (factor)	
Above normal volume [μL]	3.0
Above normal dilution (factor)	6
URINE	
Normal volume [μL]	3.0
Normal dilution (factor)	1
Below normal volume [μL]	
Below normal dilution (factor)	
Above normal volume [μL]	3.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [μL]	3.0
Normal dilution (factor)	1
Below normal volume [μL]	
Below normal dilution (factor)	
Above normal volume [μL]	3.0
Above normal dilution (factor)	6
CSF	
Normal volume [μL]	3.0
Normal dilution (factor)	1
Below normal volume [μL]	
Below normal dilution (factor)	
Above normal volume [μL]	3.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μL]	3.0
Normal dilution (factor)	1
Below normal volume [μL]	
Below normal dilution (factor)	
Above normal volume [μL]	3.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	#
URINE	
PLASMA	#
CSF	
Whole blood	
Gender	Female
Age	
SERUM	#
URINE	
PLASMA	#
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details		
Calibrator list	Concentration	
Cal. 1/Blank	0	
Cal. 2	*	
Cal. 3		
Cal. 4		
Cal. 5		
Cal. 6		
	<b>Max delta abs.</b>	
Cal. 1	0.002	
Cal. 2	0.005	
Cal. 3		
Cal. 4		
Cal. 5		
Cal. 6		
Drift limit [%]	0.80	

Calculations	
Model	X
Degree	1

\* Enter calibrator value

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