respons®920

Alkaline phosphatase FS*

IFCC mod. 37°C

Order Information

Cat. No.	Kit size
1 0441 99 10 920	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of alkaline phosphatase (AP) in serum or plasma on respons®920.

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].

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

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 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.

DiaSys respons containers provide protection from light.

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. 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.
6. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagent is 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. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function.	
Limit of detection**	2 U/L
Onboard stability	8 days
Calibration stability	8 days

Interfering substance	**Interferences ≤ 10% up to**
Ascorbate	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	100 mg/dL
Lipemia (triglycerides)	2000 mg/dL

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

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	71.1	134	225
CV [%]	1.68	0.89	1.02
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	64.4	141	197
CV [%]	3.31	3.85	2.37

Method comparison (n=110)	
Test x	DiaSys Alkaline phosphatase FS (Hitachi 917)
Test y	DiaSys Alkaline phosphatase FS (respons®920)
Slope	1.01
Intercept	–2.30 U/L
Coefficient of correlation	1.00

** lowest measurable concentration 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 [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.

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* Fluid Stable

respons®920

Alkaline phosphatase FS (IFCC mod. 37 °C)

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	AP				Auto Rerun		☐
Report Name	:	Alkaline Phosphatase				Online Calibration		☐
Unit	:	U/L	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	405	Secondary	:	700	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	AP R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	AP R2
M2 Start	:	21	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	2.50	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.0000			
Technical Minimum	:	2.0	Technical Maximum	:	1400.0			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	AP		
Sample Type	:	Serum		

Sample Volumes

Normal	:	3.00 µL	Dilution Ratio	:	1 X
Increase	:	6.00 µL	Dilution Ratio	:	1 X
Decrease	:	2.00 µL	Dilution Ratio	:	1 X
Standard Volume	:	3.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	AP		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (U/L)	Upper Limit (U/L)
Normal	:	53.00	128.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other