respons®910

Alkaline phosphatase FS (IFCC mod. 37 °C)

Diagnostic reagent for quantitative in vitro determination of alkaline phosphatase (AP) in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 0441 99 10 920
4 twin containers for 200 tests each

Method

Kinetic photometric test, according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine)

Principle

p-Nitrophenylphosphate + H_2O $\xrightarrow{AP}$ 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 and contamination is avoided. Do not freeze the reagents! Reagents must be protected 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 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. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, 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 actions 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 AP
(in case of higher activities re-measure samples after manual dilution or use rerun function).

Limit of detection**	3 U/L AP
On-board stability	7 days
Calibration stability	7 days

Interfering substance	Interferences < 10%	AP [U/L]
Ascorbate	up to 30 mg/dL	154
Hemoglobin	up to 100 mg/dL	74.2
	up to 100 mg/dL	310
Bilirubin, conjugated	up to 80 mg/dL	95.2
	up to 80 mg/dL	182
Bilirubin, unconjugated	up to 70 mg/dL	94.9
	up to 70 mg/dL	188
Lipemia (triglycerides)	up to 2200 mg/dL	98.6
	up to 2200 mg/dL	202

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

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	76.6	122	229
Coefficient of variation [%]	1.62	1.44	1.81
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	73.7	127	213
Coefficient of variation [%]	4.04	4.83	3.13

Method comparison (n=117)	
Test x	DiaSys Alkaline phospatase FS (Hitachi 911)
Test y	DiaSys Alkaline phospatase FS (respons®910)
Slope	1.049
Intercept	-4.67 U/L
Coefficient of correlation	0.9996

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

AP [U/L] x 0.0167 = AP [µkat/L]

Reference Range

Adults [3]

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

Adults [4]

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

Children [5]

	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 – 5.32
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 – 6.51
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. 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: AACC Press, 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 8C. 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.

Manufacturer

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IVD CE

respons®910

Alkaline phosphatase FS IFCC 37 °C

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
Name:	AP
Shortcut:	
Reagent barcode reference:	014
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	40
Blanc correction	Yes
Main wavelength:[nm]	405
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	6:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	1.4
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	3
Concentration technical limits-Upper	1400
SERUM	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	Male
Age	20 - 50 a
SERUM	>=53.0 <=128
URINE	
PLASMA	>=53.0 <=128
CSF	
Genre	Female
Age	20 - 50 a
SERUM	>=42.0 <=98
URINE	
PLASMA	>=42.0 <=98
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.015
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value