SPECTRUM

The Creative Approach to Bioscience

ALKALINE PHOSPHATASE
Single Reagent
(Kinetic - IFCC method)

REF: 217 001 (2 x 25 ml) 50 test
REF: 217 002 (4 x 25 ml) 100 test
REF: 217 003 (4 x 50 ml) 200 test
REF: 217 004 (4 x100 ml) 400 test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics liquizyme Alkaline Phosphatase reagent is intended for the in-vitro quantitative, diagnostic determination of ALP in human serum on both automated and manual systems.

Background

Alkaline phosphatase (ALP) catalyzes the hydrolysis of a wide variety of physiologic and non-physiologic phosphoric acid esters in alkaline medium (pH optimum 10). The liver and biliary tract are the source of alkaline phosphatase in normal sera. Normal alkaline phosphatase levels are age dependent being higher in children and adolescents in comparison to adults. ALP is one of the tests of choice for evaluating cholestasis and obstructive juandice. Elevated levels are found in many diseases including hepatitis, cirrhosis, malignancy and in bone diseases.

Method

Kinetic method according to the International Federation of Clinical Chemistry (IFCC)

Assay Principle

P-Nitrophenyl phosphate is converted to p-Nitrophenol and phosphate by alkaline phosphatase. The increase of absorption at 405 nm is proportional to the alkaline phosphatase concentration in the sample.

Reagents

Reagent (R)
Substrate Reagent

For further information, refer to the Alkaline phosphatase Monoreagent material safety data sheet.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation

Spectrum ALP-Single reagent is supplied ready-to-use.

Reagent Storage and Stability

The reagent is stable until expiration date stated on label when stored refrigerated at 2 - 8 ^{o}C.Once opened, the reagent is stable for 1 month at the specified temperature.

Deterioration

Do not use liquizyme ALP reagent if it is turbid or if the absorbance of the reagent is more than 2.2 at 405 nm. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen Collection and Preservation

Nonhaemolyzed fresh serum is the preferred specimen. Heparin is the only acceptable anticoagulant. Complexing anticoagulants such as citrate, oxalate and EDTA must be avoided.
Alkaline phosphatase activity may slowly increase in serum samples stored at room temperature. Previously frozen or lypholized sera may show a marked decrease in values immediately upon thawing or reconstitution.The activity then increases to the initial values, and the rate of this increase is time and temperature dependent.

Stability: 2 months at - 20 ^{o}C ; 4 weeksat 4 – 8 ^{o}C;
7 days at 20 – 25 ^{o}C

System Parameters

Wavelength	405 nm (400 – 420 nm)
Optical path	1 cm
Assay type	Kinetic
Direction	Increase
Sample : Reagent Ratio	1 : 100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	37 ^{o}C
Interval time	60 Sec.
Delay/Lag time	180 Sec.
Measurement	Against distalled Water
Reagent Blank Limits	Low 0.2 AU
	High 2.2 AU
Sensitivity	5 U/L
Linearity at 37^{o}C	750 U/L

Procedure

Pipette in a test tube:	
Reagent (R)	1.0 ml
Specimen	10 µl

Mix well and incubate at 37 ^{o}C for 60 sec.
Measure absorbance increase every 60 seconds for 3 minutes and determine the (ΔA/min).

Calculation

ALP Concentration (U/L) = ΔA/min x 5454

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	177.7	359.7
SD	1.71	1.5
CV%	0.96	0.43

Sensitivity

When run as recommended, the minimum detection limit of this assay is 5.0 U/L.

Linearity

The reaction is linear up to alkaline phosphatase concentration of 750 U/L

Interfering Substances
Serum, plasma

Haemolysis
A 200 mg/dL haemoglobin results in a 10 % negative bias.

Icterus
No significant interference up to bilirubin level of 40 mg/dL.

Lipemia
No significant interference from lipemia up to 1000 mg/dL.

Expected Values

		37°C
Males	(20 - 50) years	53-128 U/L
Males	(> 60) years	56-119 U/L
Females	(20 - 50) years	42-98 U/L
Females	(> 60) years	53-141 U/L
Childern	(1 - 12) years	<460 U/L

The reference values are to be considered as indicative only.
Every Laboratory should establish its own normal ranges.

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

5 – 750 U/L.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1.Moss DW. Alkaline phosphatase isoenzymes. Clin Chem. 1982;28:2007-2016 .
2.Moss DW, Henderson AR, Kachmar JF. Enzymes in:Tietz NW, ed. Fundamentals of clinical chemistry. 3 rd ed. Philadelphia: WB Saunders; 1987:346-421.
3.Tietz NW, Rinker AD, Shaw LM. IFCC methods for the measurement of catalytic concentration of enzymes. Part 5. IFCC method for alkaline phosphatase . J Clin Chem Clin Biochem. 1983;21:731-748.
4.Zawta B, Klein G, Bablok W. Temperaturumrechnung in der Klinischen Enzymologie? Klin lab. 1994:40:23-32. Sensitivity

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
217 001	2 x 25 ml
217 002	4 x 25 ml
217 003	4 x 50 ml
217 004	4 x 100 ml

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CE

ISO 13485:2016