Alkaline Phosphatase Kit

CliniQuant - FSR

Modified IFCC, Kinetic

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 ALP Reagent
ALPFSR-01	4 x 10ml	4 x 10ml
ALPFSR-02	5 x 20ml	5 x 20ml

INTENDED USE

This reagent is intended for quantitative determination of alkaline phosphatase in human serum.

CLINICAL SIGNIFICANCE

ALP occurs in high levels in liver, bone, intestine and placenta. Increased levels occur in hepatobiliary diseases and bone diseases. Elevated ALP occurs in pregnant women and growing children.

PRINCIPLE OF THE METHOD

The enzyme alkaline phosphatase hydrolizes the 4-NitroPhenolPhosphate to release 4-nitrophenol, under alkaline conditions. The 4-nitrophenol formed is detected spectrophotometrically at 405 nm to give a measurement of alkaline phosphatase activity in the sample.

2-amino-2-methyl-1-propanol + p-nitrophenylphosphate + H_2O
ALP
4-nitrophenol + 2-amino-2-methyl-1-propanol phosphate

KIT COMPONENTS

Composition

R1 - Alkaline Phosphatase Reagent : AMP buffer 700 mmol/l , magnesium salt 2.7 mmol/l, zinc salt 1.36mmol/l, HEDTA 2 mmol/l : 2.69mmol/l, pNPP 19.51 mmol/l.

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Stability since first opening of bottle: ≤ 60 days at 2-8 °C.

REAGENT DETERIORATION

Discard the reagent if absorbance exceeds 1.25 against distilled water at 405 nm.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma (heparinate only). Sera kept at room temperatures usually show a slight increase in activity, which varies from 1% over a 6 hour period to 3 to 6% over a 1 to 4 days period. Even in sera stored at refrigerator temperature, activity increases slowly. In frozen sera, activity decreases but slowly recovers after thawing the serum. EDTA, Citrate, and Oxalate are not suitable because of inhibition of ALP activity.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Rate
Factor	2764
Filter – 1 (nm)	405
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	60
Read Time (Sec)	120
Unit	U/L
Reaction Direction	Increase
Reference Low	42
Reference High	128
Linearity Limit	1200

TEST PROCEDURE

Dispense reagent in tube	1000 µl
Sample	20 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 2 readings at 60 seconds intervals. Calculate the ΔA/min.	

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RESULT CALCULATION

Serum/plasma: ALP U/l = ΔA/min x 2764

SI conversion factor: 1 U/l x 0.017 = 1 µkat/l

CONVERSION FACTOR

Following factors can be used for conversion of IU/l from one temperature to another.

Temperature of assay	Temperature factors		
	25°C	30°C	37°C
25°C	1.0	1.30	1.80
30°C	0.75	1.0	1.35
37°C	0.55	0.74	1.0

EXPECTED VALUES (in U/l at 37°C)

Age	Males	Females
Newborns (1-3 days)	95 – 368	95 – 368
2 – 24 months	115 – 460	115 – 460
2 – 5 years	115 – 391	115 – 391
6 – 7 years	115 – 460	115 – 460
8 – 9 years	115 – 345	115 – 345
10 – 11 years	115 – 336	115 – 437
12 – 13 years	127 – 403	92 – 336
14 – 15 years	79 – 446	78 – 212
16 – 18 years	58 – 331	35 – 124
Adults	41 – 137	39 - 118

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result. When using the recommended Calibrator (BioCal), calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARCTERISTICS

1. Linearity

The linearity is up to 1200 U/l or 20.4 µkat/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 1.8 U/l.

The limit of quantification is 5.5 U/l.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 1200 mg/dl; Bilirubin up to 10 mg/dl

Triglycerides up to 1900 mg/dl; Ascorbate up to 30 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	81.7	1.08	1.32
sample 2	208.5	1.73	0.83

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	85.0	2.8	3.3
sample 2	207	2.89	1.4

5. Methods Comparison

Comparison was done between reference ALP Reagent and CliniQuant -FSR Alkaline Phosphatase Reagent (test)

N = 20 y = 0.962x – 3.622 U/l

r^2 = 0.999

LIMITATIONS

Samples with values above 1200 U/l should be diluted with 0.9% saline, re-run and results multiplied by dilution factor

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 830 - 843.

2. Data on file: Meril Diagnostics.

IFU/ALPFSR01/00

06-11-2018

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community