ALP AMP IFCC Multipurpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL731AP	10 x 15 ml	ALP 1	2-8°C
	2 x 15ml	ALP 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of alkaline phosphatase (ALP) in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [3]

Alkaline Phosphatase catalyses the hydrolysis of naturally occurring synthetic substrates. The natural substrates upon which they act in the body are not known. The enzyme consists of 4 structural genotypes and is present in a variety of tissues including bone, liver, intestine, placenta, kidney and spleen. Measurements of alkaline phosphatase are used in the diagnosis of hepatobilary disease and bone disease associated with increased osteoblastic activity. Due to the increased osteoblastic activity associated with bone growth in children and juveniles, reference ranges vary very significantly with age groups.

PRINCIPLE OF THE TEST: [1, 2]

The procedure has been formulated in accordance with the recommendations of the IFCC.

P-Nitrophenol-Phosphate + H_2O $\xrightarrow{ALP}$ p-Nitrophenol + Phosphate

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Colourless liquid.
Reagent 2: Pale yellow liquid. (Tends to darken with age but this has no effect on the assay[4]).
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument applications available upon request.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	AMP, pH 10.4	0.35 mol/l
	Zinc Sulphate	1 mmol/l
	HEDTA	2 mmol/l
	Magnesium Acetate	2 mmol/l
Reagent 2	p-Nitrophenyl-Phosphate	16 mmol/l

REAGENT PREPARATION AND STABILITY:

Before use, mix each reagent by gently inverting each bottle.
If stored and handled properly, unopened components are stable until the expiry date stated on the label
Monoreagent procedure: Add 1 volume of Reagent 2 to 5 Volumes of Reagent 1.
Working reagent is stable 4 weeks at 2-8°C.
Bireagent procedure: Liquid reagent 1 and 2 are ready for use.
Once open, components are stable until expiry date on label if store and handled properly

TYPE OF SPECIMEN: [3]

Use serum or heparinised plasma, free of haemolysis, as specimen.
Do Not Use Citrate, Oxalate and EDTA.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/plasma should be separated from cells within 1 hour after collection. Sample should be analysed as soon as possible but no later than 4 hours after collection.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932		N/A

Assay procedure:

Wavelength: λ: 405 nm (410 nm)
Temperature: 25°C (30°C or 37°C)
Optical path: 1 cm light path.

MONOREAGENT PROCEDURE:	Blank	Calibrator	Sample
Working reagent	1000 µL	1000 µL	1000 µL
Sample	----	----	40 µL
Calibrator	----	40 µL	----
Gently mix sample and reagent and incubate for 1 minute, then read absorbance after a further 1, 2 and 3 minutes. Calculate the absorbance. Calculate the absorbance change (ΔOD/min) per minute.			

BIREAGENT PROCEDURE:	Blank	Calibrator	Sample
Reagent 1	1000 µL	1000 µL	1000 µL
Sample	----	----	40 µL
Calibrator	----	40 µL	----
Gently mix and Incubate at 37°C for 2 minutes			
Reagent 2	200 µL	200 µL	200 µL
Gently mix and incubate for 1 minute, then read absorbance after a further 1, 2, 3 and 4 minutes. Calculate the absorbance. Calculate the absorbance change (ΔOD/min) per minute.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- Daily.
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory's Q.C. Programme.

EXPECTED VALUES: [3]

AACC/IFCC reference method in Serum	Values UL	Values µkat/L	Temperature
Men (20 to 50 years)	53 - 128	0.88 – 2.13	37°C
Men (over 60 years)	56 - 119	0.93 – 1.98	37°C
Women (20 to 50 years)	42 - 98	0.7 – 1.63	37°C
Women (over 60 years)	53 - 141	0.88 – 2.35	37°C

Each laboratory should establish its own reference range. ALP results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.
Linearity:
This assay is linear up to 1048 U/l (17.5 µkat/L).
For samples with a higher activity:
- Reassay using, when available, "Rerun" function. Refer relevant user's manual for instructions.
- *Or*, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result obtained by 2.

Interfering substances:
Results of study are as follows:

Bilirubin (mixed isomers): Less than 10% interference up to 600 µmol/L Bilirubin.
Haemolysis: Less than 10% interference up to 5 g/L Haemoglobin.
Lipemia: Less than 10% interference up to 2.5 g/L Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.4 U/L (0.00668µkat/L)

Precision:

Within Run N = 20	Mean (U/L)	SD	% CV	Between Run N = 20	Mean (U/L)	SD	% CV
Level 1	102.6	0.65	0.63	Level 1	102.5	2.13	2.08
Level 2	353.6	4.73	1.34	Level 2	366.3	7.40	2.02

Method Comparison:
Using 50 samples, a comparison, between this ALP AMP test (y) and another commercially available this test (x), gave the following results:

y = 0.855x – 0.321	r = 0.999	Sample range: 19 to 428 U/L(0.32-7.1µkat/L)

BIBLIOGRAPHY:

1. Tietz NW et al. J Clinical Chemistry Clinical Biochemistry. 1983; 21:731-748.
2. Mathieu M et Al. L'Information du Biologiste. 1980; 45.
3. Burtis CA., Ashwood ER.Tietz Fund. Of Clin. Chem. 5th ed.; 30-54, 367 and 1002. Product Stability and Risk Analysis results on file at Glenbio Ltd.

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	CE	CE Mark - Device complies with the Directives 98/79/EC
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

GLENBIO LTD
10 Kilbegs Road, Antrim, Co. Antrim, BT41 4NN
Tel/Fax: +44(0)2879659842
Email: info@glenbio.com
Web: www.glenbio.com

EC REP
GLENBIO IRELAND LTD
17b Fota Business Park, Carrigtwohill, Co. Cork,
T45 PK77, Ireland

Revision: 02 Issued on: 20 July 2021