ALKALINE PHOSPHATASE

Alkaline Phosphatase.p-Nitrophenylphosphate Liquid

Product information

24AST01-A	**Meditest GOT/AST**	**4x40 mL 2x20 mL**
24AST01-AU	**Meditest GOT/AST**	**4x40 mL 2x20 mL**
24AST01-AB	**Meditest GOT/AST**	**4x40 mL 2x20 mL**
24AST01S	**Meditest GOT/AST**	**4x40 mL 2x20 mL**
24AST01-AR	**Meditest GOT/AST**	**4x40 mL 2x20 mL**

Purpose

In vitro assay for the quantitative determination of Alkaline Phosphatase (ALP) in human serum and plasma.

Summary

Alkaline phosphatases are enzymes found in almost all tissues of the body, especially in bones, liver, placenta, intestines and kidneys... Both increases and decreases in plasma levels are of clinical significance.

The most likely causes of increased ALP levels are: Paget's bone disease, liver obstructions, hepatitis, medication-

The most likely causes of a decrease in ALP levels are: Cretinism and vitamin C deficiency[1,5,6]. Clinical diagnosis should be made taking into account all clinical and laboratory data.

Test Prensibi

Alkaline phosphatase (ALP) catalyzes the hydrolysis of p-nitrophenylphosphate (pNPP) at pH 10.4, releasing p-nitrophenol and phosphate according to the following reaction:

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

The rate of p-nitrophenol formation, measured photometrically, is proportional to the catalytic concentration of alkaline phosphatase present in the[sample1,2]

Reagents - working solutions

R 1 Buffer	Diethanolamine (DEA) pH 10.4 Magnesium chloride	1 mmol/L 0.5 mmol/L
R 2 Substrate	p-Nitrophenylphosphate (pNPP)	10 mmol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.

Take the necessary protective measures to prevent users from becoming infected during operation.

Warning

H315 It causes irritation on the skin.

H319 It causes severe irritation to the eye.

Prevention:

P264 After handling, wash the skin thoroughly.

P280 Wear protective gloves/ eye protection/face protection.

Answer:

P302 + P352 IF SMEARED ON THE SKIN: Rinse with plenty of water.

P332 + P313 If skin irritation occurs: Seek medical advice/help.

P337 + P313 If eye irritation persists: Seek medical advice/help.

P362 + P364 Remove contaminated clothing and wash it before reuse.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.

Do not use reagents after the expiration date. Signs of reactive decay: Presence of particles and turbidity- 1.00 < empty absorbance (A) at 340 nm.

Sample collection and preparation

Use only suitable tubes and collection containers to collect and prepare specimens. Only the samples listed below have been tested and found acceptable.

Serum. Plasma: Liheparin and K2EDTA plasma

Centrifuge samples containing precipitate before performing the test. For detailed information on possible sample interactions, see the limitations and interactions section. Sample stability claims were determined by the manufacturer based on experimental data or reference literature and only for the temperatures/time frames specified in the method sheet. It is the responsibility of each laboratory to use all available references and/or their own work to determine specific stability criteria for their laboratory.

Stability: 7 days at 2025 °C
7 days at 48 °C
2 months at -20 °C

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Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . . . . . 405 nm
Cuvette: . . . . . 1 cm light path
Temperature: . 25ºC /30ºC/37ºC 2.Set the appliance to zero with distilled water.
3.Place the pipettes in a cuvette.

WR (mL)	1,2
Sample (µΛ)	20

4.Mix, incubate for 1 minute.
5. Read the initial absorbance (A) of the sample, start the stopwatch, and read the absorbances at 1-minute intervals for 3 min.
6. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/µιν).

Calculation

ΔA/min x 3300 = U/L of ALP

One international unit (IU) is the amount of enzyme that converts 1 µmol substrate per minute under standard conditions. The concentration is expressed in units per liter of sample (U/L).

Conversion factor: U/L x 0.0167 = µkat/L

Expected values

Adults
Males (n = 221) 40129 U/L (0.672.15 µkat/L)
Women (n = 229) 35104 U/L (0.581.74 µkat/L)
Kids
Male Age
0-14 days 83248 U/L (1.394.14 µkat/L)
15 days old - < 1 year old 122-469 U/L (2.04-7.83 µkat/L)
1-< 10 years 142-335 U/L (2.37-5.59 µkat/L)
10 - < 13 years 129-417 U/L (2.15-6.96 µkat/L)
13 - < 15 years 116-468 U/L (1.94-7.82 µkat/L)
15 - < 17 years 82-331 U/L (1.37-5.53 µkat/L)
17 - < 19 years 55-149 U/L (0.92-2.49 µkat/L)
Daughter
Age
0-14 days old 83-248 U/L(1.39-4.14 µkat/L)

15 days old - < 1 year old 122-469 U/L (2.04-7.83 µkat/L)
1 - < 10 years 142-335 U/L (2.37-5.59 µkat/L)
10 - < 13 years 129-417 U/L (2.15-6.96 µkat/L)
13 - < 15 years 57-254 U/L (0.95-4.24 µkat/L)
15 - < 17 years 50-117 U/L (0.84-1.95 µkat/L)
17 - < 19 years 45-87 U/L (0.75-1.45 µkat/L)

*37 ^{0}C are the values measured.

These values are for orientation purposes; Each laboratory should establish its own reference range

Limitations

Criterion: Recovery within 10% of baseline at 30 U/L (0.50 µcat/L) AST activity within ± of baseline.
Icterus: No apparent interaction for conjugated and unconjugated bilirubin until the I index is 60 (approximate concentration of conjugated and unconjugated bilirubin: 1026 µmol/L or 60 mg/dL).
Hemolysis: No apparent interaction until the H index is 40 (approximate hemoglobin concentration: 25.6 µmol/L or 40 mg/dL). Since the analyte level in erythrocytes is higher than in normal serum, contamination with erythrocytes will increase the results. The level of interaction may vary depending on the analyte content in fragmented erythrocytes.
Lipemia (Intralipid): No obvious interaction until the L index is 150. There is a weak correlation between the L index (which corresponds to turbidity) and the concentration of triglycerides. Lipemic specimens may cause the Abs warning sign to be given >.
Drugs: No interactions were found at therapeutic concentrations when common drug panels were used. Physiologic plasma concentrations of Sulfasalazine or Sulfapyridine may lead to false results.

Performance characteristics

Measuring range: 0.6845-1200 U/L
If the results obtained are greater than the linearity limit, dilute the sample by 1/10 with 9 g/L NaCl and multiply the result by 10.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	174	443	175	434
SD	0,72	1,56	6,88	11,93
CV (%)	0,41	0,35	3,93	2,75

Sensitivity: 1 U/L = 0.0003 ΔA/min
Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:
Correlation coefficient (r)²: 0, 99938.
Regret Formula y= 1,025x - 1,105

The results of the performance characteristics depend on the analyzer used.

References

1. Wenger C. et al. Alkaline phosphatase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1094-1098.
2. Rosalki S et al. Clin Chem 1993; 39/4: 648-652.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

Medios Medikal Bilişim Danışmanlık Tic. Ltd. Şti.
Güzelevler Mah. Çınar Cad. No: 5 Yüreğir/Adana