INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantification of global activity of the alkaline phosphatase enzyme in human serum or plasma.

GENERALITIES (1)

Alkaline phosphatase (ALP) is found in many tissues, including bone, liver, intestine, kidney, and placenta. Serum ALP measurements are of particular interest in the investigation of two groups of conditions: hepatobiliary diseases (hepatitis, cirrhosis or malignancy) and bone diseases associated with increased osteoblastic activity (child’s rickets with D vitamin deficiency, Paget’s disease, hyperparathyroidism in the skeleton, metastatic carcinoma).

PRINCIPLE (1) (4) (5)

Optimized method based on DGKC (German Society of Clinical Chemistry, 1972) and SCE (Scandinavian Society of Clinical Chemistry) recommendations.
In alkaline solution, ALP catalyzes the hydrolysis of p-nitrophenyl phosphate in p-nitrophenol and phosphate.
The rate of formation of p-nitrophenol, proportional to the ALP activity, is measured at 405 nm.

REAGENTS

R1 ALKALINE PHOSPHATASE Buffer
D.E.A. (Diethanolamine) buffer pH 10 (25°C) 1 mol/L
Magnesium Chloride 0.5 mmol/L
Preservative
Danger Eye Dam..1: H318 – Causes serious eye damage
P280: Wear protective gloves/protective clothing/eye protection/face protection, P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing,
P310: Immediately call a POISON CENTER or doctor/physicians. For more details refer to current Material Safety Data Sheet (MSDS).
Classification due to: Diethanolamine 2,5 - < 10%
For more details, refer to SDS (Safety data sheet)

R2 ALKALINE PHOSPHATASE Substrate
p-nitrophenyl phosphate 10 mmol/L
According to 1272/2008 regulation, this reagent is not classified as dangerous
Once reconstituted: Working Reagent is classified as vial R1.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

REAGENTS PREPARATION

Use a non-sharp instrument to remove the cap.
Add promptly the contents of vial R2 into vial R1.
Mix gently and wait for complete dissolution.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when stored and used as described, reagents are stable:
Unopened:
- Until expiry date stated on the label of the kit.
- Reconstitute immediately substrate (vial R2)
- Contents of vial R1 (Buffer) is stable at least 6 months.

Once reconstituted:
- Transfer requested quantity and store in the original vial at 2-8°C
- Working reagent is stable at least for 30 days.
- Discard reagent if cloudy or if absorbance at 405 nm is > 0.800.
- Don’t use working reagent after expiry date of the Kit.

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolysed serum or heparinized plasma immediately refrigerated.
ALP activity is stable in the specimen for:
- 2-3 days at 2-8°C.
- 1 month at –25°C.

LIMITATIONS (3)

Avoid hemolyzed serum.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer
QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- External quality control program.
  It is recommended to control in the following cases:
  - At least once a run.
  - At least once within 24 hours.
  - When changing vial of reagent.
  - After maintenance operations on the instrument.

If control is out of range, apply following actions:
1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the test with a new vial of reagent.
4. If control is still out of range, please contact BIOLAB O technical support or your local Agent.

REFERENCES

(3) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-26 to 3-35