

## Overview

### Useful For

Diagnosis and assessment of severity of metabolic bone disease including Paget disease, osteomalacia, and other states of high bone turnover

Monitoring efficacy of antiresorptive therapies including postmenopausal osteoporosis treatment

The assay is **not intended** as a screening test for osteoporosis.

Measurements of bone turnover markers are **not useful for** the diagnosis of osteoporosis; diagnosis of osteoporosis should be made on the basis of bone density.

### Method Name

Immunoenzymatic Assay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Collection Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.6 mL

### Specimen Minimum Volume

0.5 mL

### Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	90 days	
	Ambient	7 days	

## Clinical & Interpretive

### Clinical Information

Bone alkaline phosphatase (BAP) is the bone-specific isoform of alkaline phosphatase. A glycoprotein that is found on the surface of osteoblasts, BAP reflects the biosynthetic activity of these bone-forming cells. BAP has been shown to be a sensitive and reliable indicator of bone metabolism.(1)

Normal bone is constantly undergoing remodeling in which bone degradation or resorption is balanced by bone formation. This process is necessary for maintaining bone health. If the process becomes uncoupled and the rate of resorption exceeds the rate of formation, the resulting bone loss can lead to osteoporosis and, consequently, a higher susceptibility to fractures.

Osteoporosis is a metabolic bone disease characterized by low bone mass and abnormal bone microarchitecture. It can result from a number of clinical conditions including states of high bone turnover, endocrine disorders (primary and secondary hyperparathyroidism and thyrotoxicosis), osteomalacia, kidney failure, gastrointestinal diseases, long-term corticosteroid therapy, multiple myeloma, and cancer metastatic to the bones.(2)

Paget disease is another common metabolic bone disease caused by excessive rates of bone remodeling resulting in local lesions of abnormal bone matrix. These lesions can result in fractures or neurological involvement. Antiresorptive therapies are used to restore the normal bone structure.

### Reference Values

#### Males

<2 years: 25-221 mcg/L

2-9 years: 27-148 mcg/L

10-13 years: 35-169 mcg/L

14-17 years: 13-111 mcg/L

Adults: < or =20 mcg/L

#### Females

<2 years: 28-187 mcg/L

2-9 years: 31-152 mcg/L

10-13 years: 19-177 mcg/L

14-17 years: 7-41 mcg/L

#### Adults

Premenopausal: < or =14 mcg/L

Postmenopausal: < or =22 mcg/L

### Interpretation

Bone alkaline phosphatase (BAP) concentration is high in Paget disease and osteomalacia.(3)

Antiresorptive therapies lower BAP from baseline measurements in Paget disease, osteomalacia, and osteoporosis. Several studies have shown that antiresorptive therapies for management of osteoporosis patients should result in at least a 25% decrease in BAP within 3 to 6 months of initiating therapy.(4,5) BAP also decreases following antiresorptive therapy in Paget disease.(6)

When used as a marker for monitoring purposes, it is important to determine the critical difference (or least significant change). The critical difference is defined as the difference between 2 determinations that may be considered to have clinical significance. The critical difference for this method was calculated to be 25% with a 95% confidence level.(1)

### **Cautions**

Assay results should only be used in conjunction with information available from the clinical evaluation of the patient and other diagnostic procedures.

Human antimouse or other heterophile antibodies may be present in patient specimens. Although the assay has been specifically formulated to minimize their effects on the assay, results from patients known to have these antibodies should be carefully evaluated.

Liver-derived alkaline phosphatase (ALP) has some cross-reactivity in this assay: 100 U/L of liver ALP activity gives a result of 2.5 mcg/L to 5.8 mcg/L. Accordingly, serum specimens with significant elevations of liver ALP activity may yield elevated results.

### **Clinical Reference**

1. Kress BC: Bone alkaline phosphatase: methods of quantitation and clinical utility. *J Clin Ligand Assay*. 1998;21(2):139-148
2. Kuo TR, Chen CH: Bone biomarker for the clinical assessment of osteoporosis: recent developments and future perspectives. *Biomark Res*. 2017 May;5:18. doi: 10.1186/s40364-017-0097-4
3. Sharma U, Pal D, Prasad R: Alkaline phosphatase: an overview. *Indian J Clin Biochem*. 2014 Jul;29(3):269–278. doi: 10.1007/s12291-013-0408-y
4. Kress BC, Mizrahi IA, Armour KW, et al: Use of bone alkaline phosphatase to monitor alendronate therapy in individual postmenopausal osteoporotic women. *Clin Chem*. 1999 Jul;45(7):1009-1017
5. Garnero P, Darte C, Delmas PD: A model to monitor the efficacy of alendronate treatment in women with osteoporosis using a biochemical marker of bone turnover. *Bone*. 1999 Jun;24(6):603-609
6. Raisz L, Smith JA, Trahiotism M, et al: Short-term risedronate treatment in postmenopausal women: Effects on biochemical markers of bone turnover. *Osteoporos Int*. 2000;11:615-620

### **Performance**

#### **Method Description**

The instrument used is a Beckman Coulter Unicel DXI 800. The Access Ostase assay is a one-step immunoenzymatic assay used to measure bone alkaline phosphatase (BAP) in human serum. The assay utilizes a mouse monoclonal antibody specific to BAP and paramagnetic particles coated with goat antimouse antibodies. BAP in the patient's specimen binds to the anti-BAP mouse antibody, which in turn is captured by the solid phase antimouse antibody. After washing to remove any unbound material, a chemiluminescent substrate is added to the reaction vessel. The BAP

present acts on the substrate to produce light, which is measured with a luminometer. The amount of light produced is directly proportional to the amount of BAP in the specimen. The amount of analyte in the specimen is determined from a stored, multipoint calibration curve.(Package insert: Access Ostase. Beckman-Coulter; 2019)

## PDF Report

No

## Day(s) Performed

Monday through Saturday

## Report Available

2 to 3 days

## Specimen Retention Time

9 days

## Performing Laboratory Location

Rochester

## Fees & Codes

### Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

### Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

### CPT Code Information

84080

### LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BAP	Bone Alkaline Phosphatase, S	17838-4

Result ID	Test Result Name	Result LOINC® Value
BAP	Bone Alkaline Phosphatase, S	17838-4