

Bone-Specific Alkaline Phosphatase (Ostase)

MDL Test Number: 658

Methodology: Immunoassay

CPT Codes: 84080



Specimen Collection Platform:

Serum in Serum Separator Tube (SST)

Turnaround Time:

24 - 72 hours

Stability:

Room temperature

Test Additions*:

30 days to add tests

Specimen Collection:



1. Immediately after blood collection, invert the tube(s) gently 5 times to ensure mixing of clot activator.



2. Allow the tube to rest upright for at least 30 minutes after collection to ensure proper clotting.



3. Centrifuge for at least 15 minutes at 2200-2500 RPM within one hour of collection.



4. Do not remove the stopper or pour off serum.



What is Bone-Specific Alkaline Phosphatase (Ostase)?

Bone is rebuilt continuously throughout life. The cells that lay down new bone, called osteoblasts, release an enzyme into the blood as they work, and measuring that enzyme gives a picture of how much bone building is going on. The enzyme is alkaline

phosphatase, and the liver releases a very similar form of it, so a routine alkaline phosphatase result mixes the two together. This test measures the bone form on its own.

Levels follow how fast bone is being turned over rather than how much bone there is. In women, the level is comparatively low through the reproductive years and rises after menopause, because the loss of estrogen speeds up bone turnover. The other useful feature is speed: treatment for thinning bones changes this marker within three to six months, while a bone density scan may take up to two years to show the same thing. That is why it is used mainly to follow treatment rather than to make a diagnosis.

Why test for Bone-Specific Alkaline Phosphatase (Ostase)?

This test is used to follow how active bone turnover is, and how it responds to treatment. It is commonly ordered to:

- **Check whether treatment for osteoporosis is working**, months before a repeat bone density scan could answer the same question. A fall of about a quarter from the level before treatment is what the manufacturer regards as a real response.
- **Follow Paget's disease of bone**, where it is used after the diagnosis has been made on X-rays to track how active the disease is and how well treatment is working.
- **Assess bone turnover in other metabolic bone diseases**, including overactive parathyroid glands, softening of the bone from long-standing vitamin D deficiency, and the bone changes of advanced kidney disease.
- **Work out how much of a raised routine alkaline phosphatase result is coming from bone** rather than from the liver, when that is not clear from the rest of the picture.
- **Look at what has happened to bone turnover after menopause**, and at whether hormone therapy has brought it back down.
- **Alongside vitamin D and parathyroid hormone**, which MDL offers as tests 659 and 618. A raised bone alkaline phosphatase means something different when vitamin D is deficient or the parathyroid glands are overactive, because both drive bone turnover independently, and the three results are normally interpreted together.
- **Look for a build-up of too much iron**, including in people who receive blood transfusions regularly.



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Special Instructions:

- **Bone treatments must be listed:** Bisphosphonates, hormone therapy, raloxifene, and calcitonin all lower this marker, and that is a real effect on bone rather than an effect on the test. The manufacturer tested these medicines and found that none of them interferes with the measurement itself. Current treatment, and when it was started, should be on the request, because a result means something different before and after it begins.
- **Timing when treatment is being followed:** A sample taken before treatment starts gives the baseline that every later result is compared against. The manufacturer's studies measure the response again at three and six months. Without a baseline, a single result is much harder to interpret.
- **Liver conditions should be noted:** The liver releases a closely related enzyme that this test picks up in part, so any liver condition, and any medicine that affects the liver, should be listed on the request.
- **Comparing results over time:** Different laboratories and different methods for this marker do not give the same number, and the manufacturer advises that the method be kept the same while a patient is being followed. Repeat testing should be done at the same laboratory whenever possible.

Limitations:

Every laboratory test has limits. For this test, the main ones are:

- The liver form of the enzyme is picked up in part. In someone with liver disease, or with a raised routine alkaline phosphatase whose source is not known, a high result may not be coming from bone at all. It should be read alongside the routine alkaline phosphatase and the liver tests.
- Only a fairly large change is a real change. The manufacturer calculates that a difference of less than about 25% between two results can be accounted for by natural variation and by the test itself, so a smaller change should not be read as a response to treatment.
- This is not a screening test. The manufacturer states that it is not recommended for detecting osteoporosis in the general population, and that it cannot measure the rate at which bone is being built. It indicates how active bone turnover is; it does not diagnose why.
- A normal result does not rule out metabolic bone disease. The manufacturer notes that patients whose disease is not very active often have levels that sit within the expected figures.
- Rarely, antibodies that some people carry after routine contact with animals or animal products can interfere with tests built this way and produce a result that does not fit the clinical picture.
- A bone-specific alkaline phosphatase result is one piece of a larger picture. It is meant to be read together with the patient's symptoms, medical history, and other test results — never on its own.

Reference Range(s):

Results are reported in micrograms per liter ($\mu\text{g/L}$). The manufacturer does not publish a range with a low end. It publishes a middle value and an upper figure for three groups of apparently healthy adults aged 20 to 89, measured on the earlier version of this test and carried across to the current one. Postmenopausal women sit higher than premenopausal women, which reflects the faster bone turnover that follows the loss of estrogen, but the manufacturer is explicit that the three groups overlap considerably. Because no lower figure is published, a low result cannot be judged against one.

- **Premenopausal females:** median 8.5, **95th percentile 14.3 $\mu\text{g/L}$**
- **Postmenopausal females:** median 12.5, **95th percentile 22.4 $\mu\text{g/L}$**
- **Adult males:** median 11.6, **95th percentile 20.1 $\mu\text{g/L}$**

A result outside these figures is not automatically a problem, and a result inside them does not rule one out. Only the ordering provider can interpret what a given number means for a given patient. Patients should always go by the reference range printed on their own laboratory report.

Analyte	Disorder	Expected Value*
Ostase	Osteomalacia	↑
Ostase	Vitamin D deficiency	↑
Ostase	Primary hyperparathyroidism	↑
Ostase	Hypoparathyroidism	↓
Ostase	Paget's disease of bone	↑↑

*↑ – Increased ↓ – Decreased ↑↑ – Markedly Increased.

What are some references that discuss the medical necessity of testing Bone-Specific Alkaline Phosphatase (Ostase)?

1. Singer FR, et al. Paget's disease of bone: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*, **99**, 4408–4422 (2014).
2. LeBoff MS, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*, **33**, 2049–2102 (2022).
3. Minisola S, et al. Osteomalacia and vitamin D status: a clinical update 2020. *JBM Plus*, **5**, e10447 (2021).
4. Demay MB, et al. Vitamin D for the prevention of disease: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*, **109**, 1907–1947 (2024).
5. Bilezikian JP, et al. Evaluation and management of primary hyperparathyroidism: summary statement and guidelines from the Fifth International Workshop. *J Bone Miner Res*, **37**, 2293–2314 (2022).
6. Khan AA, et al. Evaluation and management of hypoparathyroidism: summary statement and guidelines from the Second International Workshop. *J Bone Miner Res*, **37**, 2568–2585 (2022).



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