Test Definition: OSCAL

Osteocalcin, Serum

Overview

Useful For

Monitoring and assessing the effectiveness of antiresorptive therapy in patients treated for osteopenia, osteoporosis, Paget disease, or other disorders in which osteocalcin levels are elevated

As an adjunct in the diagnosis of medical conditions associated with increased bone turnover, including Paget disease, cancer accompanied by bone metastases, primary hyperparathyroidism, and renal osteodystrophy

This test is **not useful for** the diagnosis of osteoporosis.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation:

1. Fasting: 12 hours, required

2. For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross	Reject

hemolysis	
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Ambient	72 hours	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information

Osteocalcin, the most important noncollagen protein in bone matrix, accounts for approximately 1% of the total protein in human bone. It is a 49-amino acid protein with a molecular weight of approximately 5800 Da. Osteocalcin contains up to 3 gamma-carboxyglutamic acid residues due to posttranslational, vitamin K-dependent enzymatic carboxylation. Its production is dependent upon vitamin K and is stimulated by 1,25 dihydroxy vitamin D.

Osteocalcin is produced by osteoblasts and is widely accepted as a marker of bone osteoblastic activity. Osteocalcin, incorporated into the bone matrix, is released into the circulation from the matrix during bone resorption and, hence, is considered a marker of bone turnover rather than a specific marker of bone formation. Osteocalcin levels are increased in metabolic bone diseases with increased bone or osteoid formation, including osteoporosis, osteomalacia, rickets, hyperparathyroidism, renal osteodystrophy, thyrotoxicosis, and individuals with fractures, acromegaly, and bone metastasis. By means of osteocalcin measurements, it is possible to monitor therapy with antiresorptive agents (bisphosphonates or hormone replacement therapy) in, for example, patients with osteoporosis or hypercalcemia.(1) Decrease in osteocalcin is also observed in some disorders (eg, hypoparathyroidism, hypothyroidism, and growth hormone deficiency).

Immunochemical and chromatographic studies have demonstrated considerable heterogeneity for concentrations of circulating osteocalcin in normal individuals and in patients with osteoporosis, chronic kidney failure, and Paget disease. Both intact osteocalcin (amino acids 1-49) and the large N-terminal/midregion (N-MID) fragment (amino acids 1-43) are present in blood. Intact osteocalcin is unstable due to protease cleavage between amino acids 43 and 44. The N-MID fragment, resulting from cleavage, is considerably more stable. This assay detects both the stable N-MID fragment and intact osteocalcin.

Reference Values

Males
<5 years: 19-75 ng/mL
5-9 years: 21-108 ng/mL
10-15 years: 19-159 ng/mL
16-17 years: 12-114 ng/mL
> or =18 years: 9-42 ng/mL

Females
<5 years: 14-126 ng/mL
5-9 years: 16-152 ng/mL
10-15 years: 15-151 ng/mL
16-17 years: 9-70 ng/mL
> or =18 years: 9-42 ng/mL

Interpretation

Elevated levels of osteocalcin indicate increased bone turnover.

In patients taking antiresorptive agents (bisphosphonates or hormone replacement therapy), a decrease of 20% or less from baseline osteocalcin level (ie, prior to the start of therapy) after 3 to 6 months of therapy suggests effective response to treatment.(2)

Patients with diseases, such as hyperparathyroidism, which can be cured should have a return of osteocalcin levels to the reference range within 3 to 6 months after complete cure.(3)

Cautions

Measurements of bone turnover markers are not useful for the diagnosis of osteoporosis, which should be made based on bone density or clinical history of low-trauma fracture.

Osteocalcin is cleared by the kidneys; therefore, elevations may be observed in patients with impaired kidney function without increased bone turnover.

Serum osteocalcin may not reflect bone formation in patients treated with the hormone 1,25-dihydroxy vitamin D or those with abnormalities in that hormone since osteocalcin is regulated by 1,25-dihydroxy vitamin D.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium can also rarely occur and may interfere in this assay. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Chen JT, Hosoda K, Hasumi K, Ogata E, Shiraki M. Serum N-terminal osteocalcin is a good indicator for estimating responders to hormone replacement therapy in postmenopausal women. J Bone Miner Res. 1996;11(11):1784-1792
2. Delmas PD, Eastell R, Garnero P, Seibel MJ, Stepan J; Committee of Scientific Advisors of the International Osteoporosis Foundation. The use of biochemical markers of bone turnover in osteoporosis. Committee of Scientific Advisors of the International Osteoporosis Foundation. Osteoporos Int. 2000;11(Suppl 6):S2-S17
3. Harris SS, Soteriades E, Dawson-Hughes B; Framingham Heart Study; Boston Low-Income Elderly Osteoporosis Study. Secondary hyperparathyroidism and bone turnover in elderly blacks and whites. J Clin Endocrinol Metab. 2001;86(8):3801-3804
4. Fraser W. Bone and mineral metabolism. In: Rifai N, Horvath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018:1422-1491

Performance

Method Description
The Roche Osteocalcin assay is a 2-site immunometric (sandwich) assay using electrochemiluminescence detection. Patient specimen, biotinylated monoclonal N-terminal/midregion (N-MID) osteocalcin-specific antibody, and monoclonal N-MID osteocalcin-specific antibody labeled with ruthenium react to form a complex. Streptavidin-coated microparticles act as the solid phase to which the complex binds. Voltage is applied to the electrode, inducing a chemiluminescent emission from the ruthenium, which is then measured against a calibration curve to determine the amount of osteocalcin in the patient specimen.(Package insert: Elecsys N-MID Osteocalcin. Roche Diagnostics; V 2.0 English, 11/2022)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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 account representative. 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
83937

LOINC® Information

Test Definition: OSCAL

Osteocalcin, Serum

Test ID	Test Order Name	Order LOINC® Value
OSCAL	Osteocalcin, S	2697-1

Result ID	Test Result Name	Result LOINC® Value
OSCAL	Osteocalcin, S	2697-1