Overview

Useful For
Monitoring and assessing effectiveness of antiresorptive therapy in patients treated for osteopenia, osteoporosis, Paget's 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's 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

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Patient Preparation:

1. **For 12 hours before specimen collection do not** take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

2. Patient should be fasting for 12 hours.

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Centrifuge and aliquot serum into plastic vial.

Specimen Minimum Volume
0.75 mL

Reject Due To
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 daltons. Osteocalcin contains up to 3 gamma-carboxyglutamic acid residues as a result of 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 in 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 [HRT]) in, for example, patients with osteoporosis or hypercalcemia. 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 renal 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: 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: HRT), 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 on the basis of bone density or clinical history of low-trauma fracture.

Osteocalcin is cleared by the kidneys, hence, elevations may be observed in patients with impaired renal 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.

As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from specimens taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes.

In rare cases, interference due to extremely high titers of antibodies to ruthenium or streptavidin can occur.

**Clinical Reference**


Performance

Method Description
The Roche Osteocalcin assay is a 2-site immunometric (sandwich) assay using electrochemiluminescence detection. Patient specimen, biotinylated monoclonal 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 1.0 English 01/2020)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; 5 a.m.-12 a.m.
Saturday; 6 a.m.-6 p.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
3 months

Performing Laboratory Location
Rochester

Fees and 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 U.S. 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

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