Overview

Useful For
Monitoring antiresorptive therapies (eg, bisphosphonates and hormone replacement therapy) in postmenopausal women treated for osteoporosis and individuals diagnosed with osteopenia

An adjunct in the diagnosis of medical conditions associated with increased bone turnover

Method Name
Electrochemiluminescence Immunoassay (ECLIA)

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.

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Submission Container/Tube: Plastic vial, 5 mL
Specimen Volume: 1 mL
Collection Instructions:
1. Collect specimen prior to 10 a.m.
2. Centrifuge and aliquot serum into plastic vial.

Specimen Minimum Volume
0.75 mL

Reject Due To

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<th>Gross hemolysis</th>
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Clinical & Interpretive

Clinical Information
Human bone is continuously remodeled through a process of bone formation and resorption. Approximately 90% of the organic matrix of bone is type I collagen, a helical protein that is crosslinked at the N- and C-terminal ends of the molecule. During bone resorption, osteoclasts secrete a mixture of acid and neutral proteases that degrade the collagen fibrils into molecular fragments, including C-terminal telopeptide (CTx). As bone ages, the alpha form of aspartic acid present in CTx converts to the beta form. Beta-CTx is released into the bloodstream during bone resorption and serves as a specific marker for the degradation of mature type I collagen. Elevated serum concentrations of beta-CTx have been reported in patients with increased bone resorption.

Bone turnover markers are physiologically elevated during childhood, growth, and fracture healing. The elevations in bone resorption markers and bone formation markers are typically balanced in these circumstances and are of no diagnostic value. By contrast, bone turnover markers may be useful when the bone remodeling process is unbalanced. Abnormalities in the process of bone remodeling can result in changes in skeletal mass and shape. Many diseases, in particular hyperthyroidism, all forms of hyperparathyroidism, most forms of osteomalacia and rickets (even if not associated with hyperparathyroidism), hypercalcemia of malignancy, Paget disease, multiple myeloma, and bone metastases, as well as various congenital diseases of bone formation and remodeling, can result in accelerated and unbalanced bone turnover. Unbalanced bone turnover is also found in age-related and postmenopausal osteopenia and osteoporosis.

Disease-associated bone turnover abnormalities should normalize in response to effective therapeutic interventions, which can be monitored by measurement of serum and urine bone resorption markers.

Reference Values
Males
<5 years: 242-1292 pg/mL
5-9 years: 351-1532 pg/mL
10-15 years: 447-2457 pg/mL
16-17 years: 478-1666 pg/mL
18-29 years: 238-1019 pg/mL
30-39 years: 225-936 pg/mL
40-49 years: 182-801 pg/mL
50-59 years: 161-737 pg/mL
60-69 years: 132-752 pg/mL
Test Definition: CTX
Beta-CrossLaps, Serum

> or =70 years: 118-776 pg/mL

Females
<5 years: 347-1508 pg/mL
5-9 years: 383-1556 pg/mL
10-15 years: 311-1776 pg/mL
16-17 years: 146-1266 pg/mL
18-29 years: 148-967 pg/mL
30-39 years: 150-635 pg/mL
40-49 years: 131-670 pg/mL
50-59 years: 183-1060 pg/mL
60-69 years: 171-970 pg/mL
> or =70 years: 152-858 pg/mL
Premenopausal: 136-689 pg/mL
Postmenopausal: 177-1015 pg/mL

Interpretation
Elevated levels of beta-C-terminal telopeptide (CTx) indicate increased bone resorption. Increased levels are associated with osteoporosis, osteopenia, Paget disease, hyperthyroidism, and hyperparathyroidism.

In patients taking antiresorptive agents (bisphosphonates or hormone replacement therapy), a decrease of 25% or more from baseline beta-CTx levels (ie, prior to the start of therapy) 3 to 6 months after initiation of therapy indicates an adequate therapeutic response.

Cautions
Reduced renal function may lead to reduced urinary excretion of beta-C-terminal telopeptide (CTx) and a consequent increase in the apparent serum beta-CTx concentration.

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 also 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.

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

Clinical Reference
Method Description
The Roche Beta-CrossLaps/serum assay is a 2-site immunometric (sandwich) assay using electrochemiluminescence detection. Patient specimen, biotinylated monoclonal beta-CrossLaps-specific antibody, and monoclonal beta-CrossLaps-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 beta-CrossLaps in the patient specimen. This assay is specific for crosslinked isomerized type I collagen fragments, independent of the nature of the crosslink (e.g., pyrrole, pyridinoline). The assay specificity is guaranteed through the use of 2 monoclonal antibodies, each recognizing linear beta-8AA octapeptides (EKAHD-beta-GGR). The assay, therefore, quantifies all type I collagen degradation fragments that contain the isomerized octapeptide beta-8AA twice (beta-CTX). (Package insert: Elecsys Beta-CrossLaps/serum. Roche Diagnostics; V1.0, 09/2021)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
2 weeks

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 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
82523

LOINC® Information

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