Overview

Useful For

Monitoring antiresorptive therapies (e.g., 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 this test 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: Aliquot Tube, 5 mL (T465)

Collection Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Submission Container/Tube: Plastic, 5 mL, aliquot tube

Specimen Volume: 1 mL

Collection Instructions:

1. Collect specimen prior to 10 a.m.

2. Centrifuge and aliquot serum

Specimen Minimum Volume

0.4 mL

Reject Due To
Test Definition: CTX
Beta-CrossLaps (B-CTx), S

<table>
<thead>
<tr>
<th>Hemolysis</th>
<th>Mild OK; Gross reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Frozen (preferred)</td>
<td>90 days</td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>72 hours</td>
</tr>
</tbody>
</table>

**Clinical and 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). 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**

<18 years: not established

18-30 years: 120-946 pg/mL

31-50 years: 93-630 pg/mL

51-70 years: 35-836 pg/mL
Test Definition: CTX
Beta-CrossLaps (B-CTx), S

>70 years: not established

Females

<18 years: not established

Premenopausal: 25-573 pg/mL

Postmenopausal: 104-1,008 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.

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

Testing is performed using the Roche cobas 6000 e601 analyzer and the Roche Beta-CrossLaps assay, 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 (eg, pyrrole, pyridinolines). 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: Beta-
Test Definition: CTX
Beta-CrossLaps (B-CTx), S

CrossLaps Roche Cobas. Roche Diagnostics, Indianapolis, IN. 08/2010, V3)

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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
82523

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTX</td>
<td>Beta-CrossLaps (B-CTx), S</td>
<td>41171-0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTX</td>
<td>Beta-CrossLaps (B-CTx), S</td>
<td>41171-0</td>
</tr>
</tbody>
</table>