Test Definition: CTX

Beta-CrossLaps, Serum

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:
Fasting: 12 hours, required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL Serum
Collection Instructions:
1. Collect specimen prior to 10 a.m.
2. Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

Specimen Minimum Volume

Serum: 0.75 mL

Reject Due To

Gross hemolysis	Reject

Gross lipemia	OK
Gross icterus	Reject

Specimen Stability Information

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

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

> 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 kidney 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 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.

Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Concentrations up to 1200 ng/mL may be present in specimens collected from patients taking extremely high doses of biotin up to 300 mg per day. In a study among 54 healthy volunteers, supplementation with 20 mg/day biotin resulted in a maximum serum biotin concentration of 355 ng/mL 1-hour postdose.

Clinical Reference

1. Christgau S, Bitsch-Jensen O, Hanover Bjarnason N, et al. Serum CrossLaps for monitoring the response in individuals undergoing antiresorptive therapy. Bone. 2000;26(5):505-511
2. Garnero P, Borel O, Delmas PD. Evaluation of a fully automated serum assay for C-terminal cross-linking telopeptide of type I collagen in osteoporosis. Clin Chem. 2001;47(4):694-702
3. 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

4. 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. doi:10.1007/s001980070002

5. Saint Paul LP, Debruyne D, Bernard D, Mock DM, and Defer GL. Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis. Expert Opin Drug Metab Toxicol. 2016;12:3,327-344

6. Grimsey P, Frey N, Bendig G, et al: Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. J Pharmacokinet Pharmacodyn. 2017;2(4),247-256

Performance

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 (eg, 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; 10/2022)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

2 weeks

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

82523

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CTX	Beta-CrossLaps (B-CTx), S	41171-0

Result ID	Test Result Name	Result LOINC® Value
CTX	Beta-CrossLaps (B-CTx), S	41171-0