

Overview

Useful For

Monitoring effectiveness of antiresorptive therapy in patients treated for osteoporosis or other metabolic bone disorders

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

This test is **not useful for** screening or diagnosing osteoporosis.

Highlights

Measurement of serum N-terminal telopeptide (NTx) is helpful for monitoring effectiveness of antiresorptive therapies in patients treated for osteoporosis or other metabolic bone disorders.

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: Fasting is preferred due to diurnal variation of markers and food effects

Collection Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Collection Instructions: A morning collection from fasting patients is preferred. If not possible, collect the baseline and subsequent specimens under the same circumstances (eg, at same time of day).

Specimen Minimum Volume

0.1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	28 days	
	Refrigerated	24 hours	

Clinical and Interpretive

Clinical Information

Human bone is continuously remodeled through the process of bone formation and resorption. Measurement of bone turnover markers (BTM) in serum or urine serves as an indicator of bone formation or bone resorption cellular activities. BTM are physiologically elevated during childhood, growth, and during fracture healing. The elevations in bone resorption markers and bone formation markers are typically balanced in these circumstances and of no diagnostic value. Bone diseases occur when formation and resorption are uncoupled. In these situations, BTM might serve as predictors of therapy response.

Telopeptides of type 1 collagen are the most extensively studied and used bone resorption markers. There are 2 forms depending on the cross-link forming site with collagen: the N-terminal telopeptide (NTx) and C-terminal telopeptide (CTx), which are released during collagen degradation.

In osteoporosis, a disease characterized by low bone mass and deterioration of bone tissue leading to increase skeletal fragility, measurement of BTM helps to determine treatment efficacy or patient's compliance with therapy. The advantage of measurement of BTM is that changes in response to therapy are observed within 3 to 6 months after therapy initiation; whereas changes in bone mineral density are not observed until 12 to 24 months posttherapy. Other diseases affecting the bone remodeling process, such as hyperthyroidism, all forms of hyperparathyroidism, most forms of osteomalacia and rickets (even if not associated with hyperparathyroidism), hypercalcemia of malignancy, Paget disease, multiple myeloma, bony metastases, as well as various congenital diseases of bone formation and remodeling, can result in accelerated and unbalanced bone turnover and elevation of BTM.

Reference Values

All units are reported in nmol bone collagen equivalent (BCE)

Adult (> or =18 years of age)

Males:

5.4-24.2 nmol BCE

Females:

Premenopausal: 6.2-19.0 nmol BCE

The target value for postmenopausal adult females undergoing treatment for osteoporosis is the same as the premenopausal reference interval.

Interpretation

Elevated levels of N-terminal telopeptide (NTx) indicate increased bone resorption.

A 30% or greater reduction in this resorption marker 3 to 6 months after initiation of therapy indicates a probably adequate therapeutic response.

A common target of antiresorptive therapy in the treatment of postmenopausal osteoporosis is to achieve bone markers concentrations within the premenopausal reference range.

Cautions

[Serum N-terminal telopeptide \(NTx\)](#) should not be used for the screening or diagnosis of osteoporosis. In patients with other clinical conditions known to affect bone resorption (eg; cancer metastases to bone), interpretation of serum NTx for monitoring response to osteoporosis therapy might be unreliable.

Do not interchange the Osteomark NTx serum assay values with the Osteomark NTx urine assay values, especially when monitoring therapy.

Some patients who have been exposed to animal antigens, either in the environment or as part of treatment or imaging procedures, may have circulating anti-animal antibodies present. These antibodies may interfere with the assay reagents to produce unreliable results.

Clinical Reference

1. Lee J, Vasikaran S: Current recommendations for laboratory testing and use of bone turnover markers in management of osteoporosis. *Ann Lab Med.* 2012 Mar;32(2):105-112
2. Chopin F, Biver E, Funck-Brentano T, et al: Prognostic interest of bone turnover markers in the management of postmenopausal osteoporosis. *Joint Bone Spine.* 2012 Jan;79(1):26-31
3. Hlaing TT, Compston JE: Biochemical markers of bone turnover-uses and limitations. *Ann Clin Biochem.* 2014 Mar;51(Pt 2):189-202

Performance

Method Description

The Osteomark N-terminal telopeptide (NTx) serum assay is a competitive-inhibition enzyme-linked immunosorbent assay (ELISA/EIA) for quantitative determination of NTx in human serum.

NTx epitope is adsorbed onto a 96-well microplate. Diluted samples are added to the microplate wells, followed by a horseradish peroxidase-labeled monoclonal antibody. NTx in the patient sample competes with the NTx epitope in the microplate well for antibody-binding sites. Following a wash step, the amount of labeled antibody bound is measured by colorimetric generation of a peroxide substrate. Absorbance is determined spectrophotometrically and the NTx concentration calculated using a standard calibration curve. Assay values are reported in nanomoles bone collagen equivalents per liter (nM BCE). (Package insert: Osteomark NTx Serum. Alere Scarborough, Inc; REV 05/2016)

PDF Report

No

Day(s) and Time(s) Test Performed

Thursday

Analytic Time

1 day

Maximum Laboratory Time

5 days

Specimen Retention Time

14 days

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

82523

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
SNTX	NTX-Telopeptide, S	21215-9

Result ID	Test Result Name	Result LOINC Value
65558	NTX-Telopeptide, S	21215-9