Overview

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

Monitoring effectiveness of antiresorptive therapy in patients treated for osteopenia, osteoporosis, Paget disease, or other metabolic bone disorders

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTXCT</td>
<td>Creatinine, U</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>NTXUR</td>
<td>NTX-Telopeptide, U</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Method Name

NTXUR: Chemiluminescence Immunoassay

NTXCT: Enzymatic Colorimetric Assay

NY State Available

Yes

Specimen

Specimen Type
Urine

Specimen Required

Patient Preparation: For 24 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.

Container/Tube: Plastic, 13-mL urine tube

Specimen Volume: 4 mL

Collection Instructions:

1. Collect second morning void.

2. No preservative.

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
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</thead>
</table>

Test Definition: NTXPR
NTX-Telopeptide, U

Other
Specimen with pH <5; specimen containing preservatives

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Urine</td>
<td>Frozen (preferred)</td>
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<td></td>
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<tr>
<td></td>
<td>Refrigerated</td>
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</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
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Clinical and Interpretive

Clinical Information
Human bone is continuously remodeled through a process of osteoclast-mediated bone formation and resorption. This process can be monitored by measuring serum and urine markers of bone formation and resorption. Approximately 90% of the organic matrix of bone is type I collagen, a helical protein that is cross-linked at the N- and C-terminal ends of the molecule. The amino acid sequences and orientation of the cross-linked alpha 2 N-telopeptide of type 1 collagen make it a specific marker of human bone resorption. N-terminal telopeptide (NTx) molecules are mobilized from bone by osteoclasts and subsequently excreted in the urine. Elevated levels of NTx indicate increased bone resorption.

Bone turnover markers 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. By contrast, 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 bony metastases, as well as various congenital diseases of bone formation and remodeling can result in accelerated and unbalanced bone turnover. Unbalanced bone turnover, usually without increase in 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 and formation markers.

Reference Values
All units are reported in nmol Bone Collagen Equivalents/mmol creatinine.

Adult (> or =18 years of age)

Males:
21-83 nmol BCE/mmol creatinine

Females:
Premenopausal: 17-94 nmol BCE/mmol creatinine
Postmenopausal: 26-124 nmol BCE/mmol creatinine

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Test Definition: NTXPR
NTX-Telopeptide, U

Pediatric

Males:

Tanner Stage I: 55-508 nmol BCE/mmol creatinine
Tanner Stage II: 21-423 nmol BCE/mmol creatinine
Tanner Stage III: 27-462 nmol BCE/mmol creatinine
Tanner Stage IV: <609 nmol BCE/mmol creatinine
Tanner Stage V: <240 nmol BCE/mmol creatinine

Females:

Tanner Stage I: 6-662 nmol BCE/mmol creatinine
Tanner Stage II: 193-514 nmol BCE/mmol creatinine
Tanner Stage III: 13-632 nmol BCE/mmol creatinine
Tanner Stage IV: <389 nmol BCE/mmol creatinine
Tanner Stage V: <132 nmol BCE/mmol creatinine

**Interpretation**

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

Most patients with osteopenia or osteoporosis have low, but unbalanced, bone turnover, with bone resorption dominating over bone formation. While this may result in mild elevations in bone turnover markers in these patients, finding significantly elevated urine NTx levels is atypical. Therefore, if levels are substantially elevated above the young adult reference range (>1.5- to 2-fold), the likelihood of coexisting osteomalacia, or of an alternative diagnosis as described in the Clinical Information section, should be considered.

When alternative causes for elevated NTx have been excluded in a patient with osteopenia/osteoporosis, the patient must be considered at increased risk for accelerated progression of osteopenia/osteoporosis.

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

The Negotiated Rulemaking Committee of HCFA also recommends:

"Because of significant specimen to specimen collagen crosslink physiologic variability (15%-20%), current recommendations for appropriate utilization include: 1 or 2 baseline assays from specified urine collections on separate days; followed by a repeat assay about 3 months after starting antiresorptive therapy; followed by a repeat assay in 12 months; thereafter not more than annually, if medically necessary."

**Cautions**

Very dilute specimens may not allow measurement of a urine creatinine level and, therefore, reporting of N-terminal telopeptide (NTx) values normalized to creatinine becomes impossible.
Inadvertent collection of urine for NTx measurements in a collection bottle that contains an acidic preservative results in substantial artifactual elevations of apparent NTx concentrations; such specimens are unacceptable and will be rejected.

Hemolysis and turbidity in samples may affect test results.

While the VITROS NTx test is used as an indicator of bone resorption, use of this test has not been established to predict development of osteoporosis or future fracture risk. A single NTx value cannot provide the rate of bone resorption as reported results do not contain a measure of time.

Use of this test has not been established in primary hyperparathyroidism or hyperthyroidism.

Biotin levels in urine remain elevated for up to 24 hours after oral or intravenous biotin administration.

Clinical Reference

Performance
Method Description
The Vitros N-terminal telopeptide (NTx) assay is a competitive immunoassay technique that depends on competition between NTx in the sample with a synthetic NTx peptide coated on the wells for binding by a horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-NTx). The conjugate is captured by the peptide coated on the wells and unbound materials are removed by washing.

A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent (a substituted acetalide) are added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level of light produced and prolongs the duration of light produced. The light signals are read by the Vitros Immunodiagnostic System. The amount of HRP conjugate bound is inversely proportional to the concentration of NTx in the sample. Assay values are corrected for urinary dilution by urinary creatinine analysis and expressed in nanomoles bone collagen equivalents per liter (nM BCE/L) per millimole creatinine per liter (mM creatinine/L). (Instruction manual: Vitros Instructions for Use, N-Telopeptide. Ortho-Clinical Diagnostics, Inc. GEM1426 version 6.0; Rochester, NY 14626-1501, 03/03/2016)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday, Thursday; Varies

Analytic Time
Test Definition: NTXPR
NTX-Telopeptide, U

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 or approved 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
82570
82523

LOINC® Information

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<td>NTX-Telopeptide, U</td>
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