Clinical Use

- Monitor therapeutic response in patients with metabolic bone disorders
- Predict future bone mineral density (BMD)
- Predict therapeutic response prior to initiation of antiresorptive therapy
- Detect bone metastasis in patients with various malignancies

Reference Range

Men

<table>
<thead>
<tr>
<th>Units*</th>
<th>2nd AM urine</th>
<th>24-h urine</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29 y</td>
<td>12-99</td>
<td>5-87</td>
</tr>
<tr>
<td>30-59 y</td>
<td>9-60</td>
<td></td>
</tr>
</tbody>
</table>

Women, premenopausal

<table>
<thead>
<tr>
<th>Units*</th>
<th>2nd AM urine</th>
<th>24-h urine</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-64</td>
<td></td>
<td>5-79</td>
</tr>
</tbody>
</table>

Test results within the premenopausal reference range do not rule out osteoporosis nor the need for therapy.

*nmol BCE/mmol creat; BCE, bone collagen equivalent.

Interpretive Information

- Osteoporosis
- Osteopenia
- Celiac disease
- Paget’s disease
- Primary hyperthyroidism
- Rheumatoid arthritis
- Growth hormone deficiency (non-adult onset)

- Therapeutic response (ie, decrease relative to baseline)

Clinical Background

Healthy levels of bone mineral density (BMD) are maintained by a balance between bone resorption and bone formation. N-telopeptide (NTx), the amino-terminal cross-linked peptide of type I collagen, is released during bone resorption and has been correlated with BMD T-scores. Multiple studies have shown that NTx not only correlates inversely with BMD response to therapy, but also is an early marker or predictor of BMD response. Thus, therapeutic response can be determined within 3 to 6 months of therapy rather than 1 to 2 years. Studies have also demonstrated that elevated pretreatment NTx values predict positive response to therapies such as hormone replacement therapy in postmenopausal women. In patients with malignancies, elevated levels of NTx may indicate bone metastases.

Method

- Immunochemiluminometric assay (ICMA)
- Analytical sensitivity: 10 nmol BCE/L

Specimen Requirements

Urine, 2nd morning void (36167X)

2 mL refrigerated aliquot of urine
1 mL minimum
Do not use preservatives.
Record total 24-h volume on the vial and request form.