An automated assay for the quantitative determination of bone-specific alkaline phosphatase (BAP), an indicator of osteoblastic activity, in human serum or plasma. The assay is intended for use as an aid in the management of post-menopausal osteoporosis and Paget’s disease.

Serum levels of BAP are believed to reflect the metabolic status of osteoblasts. An accurate assessment of bone metabolism is critical for determining the severity of metabolic bone disease and responses to therapy. Measurement of serum levels of BAP has been shown to be useful in evaluating patients with Paget’s disease, osteomalacia, primary hyperparathyroidism, renal osteodystrophy, osteoporosis and metastases to bone. Total alkaline phosphatase determinations have been the accepted method for the diagnosis and monitoring of patients with Paget’s disease.

Paget’s disease of bone is a common skeletal disorder in which there is a focal proliferation of the normal cellular components of bone. Paget’s disease is more prevalent than once thought with the incidence rate in certain populations at 3 – 4% in middle-aged patients and 10 – 15% in the elderly.

Features and benefits

- Exceptional sensitivity and reproducible results – providing a useful tool to identify non-adherent and non-responders to therapy.
- BAP levels are not affected by circadian variation – ease of sample collection, handling, and storage.
- BAP is cleared by the liver, not by the kidneys – levels are not affected by renal function.
- Clinically relevant measurement – as recommended in KDIGO guidelines.
- Complements the existing bone turnover panel aiding management of osteoporosis and other metabolic bone diseases.
Format: Automated spectrophotometric immunoenzymatic assay

Calibrators: Ready to use – 1 each of 2 concentration levels, 2.5 mL

Limits of Quantitation: 1.0 μg/L

Dynamic range: 1 – 75 μg/L

Reference Range:

<table>
<thead>
<tr>
<th>Population</th>
<th>Mean (μg/L)</th>
<th>SD</th>
<th>Median (μg/L)</th>
<th>Range (μg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>11.8</td>
<td>5.9</td>
<td>10.6</td>
<td>5.7 - 32.9</td>
</tr>
<tr>
<td>Pre-menopausal females</td>
<td>11.0</td>
<td>4.5</td>
<td>10.2</td>
<td>4.7 - 27.0</td>
</tr>
<tr>
<td>Post-menopausal females</td>
<td>11.8</td>
<td>6.9</td>
<td>10.4</td>
<td>5.5 - 27.1</td>
</tr>
</tbody>
</table>

Minimum sample volume: 50 μL plus dead volume

Sample Type:
- Human serum – including serum collected in serum separator tubes
- Human plasma – collected in lithium or sodium heparin tubes

Reagent Stability:
- The IDS-iSYS Ostase® BAP reagent cartridge may be stored after opening on-board the IDS-iSYS Multi-Discipline Automated System or at 2 - 8°C for up to 14 days

Calibration stability:
- The calibration of the IDS-iSYS Ostase® BAP assay is stable for up to 14 days

Time to first result: 43 minutes

Precision:

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>n</th>
<th>Mean (μg/L)</th>
<th>Within Run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>80</td>
<td>9.8</td>
<td>2.0%</td>
<td>9.0%</td>
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<tr>
<td>2</td>
<td>80</td>
<td>17.5</td>
<td>1.6%</td>
<td>7.7%</td>
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<tr>
<td>3</td>
<td>80</td>
<td>43.1</td>
<td>1.5%</td>
<td>6.5%</td>
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<tr>
<td>4</td>
<td>80</td>
<td>61.2</td>
<td>1.3%</td>
<td>6.6%</td>
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<tr>
<td>5</td>
<td>80</td>
<td>77.4</td>
<td>1.4%</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

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References: