IDS-iSYS Ostase® BAP

Bone Turnover

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 [1,2]. 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 [1-5]. 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 [6].

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.

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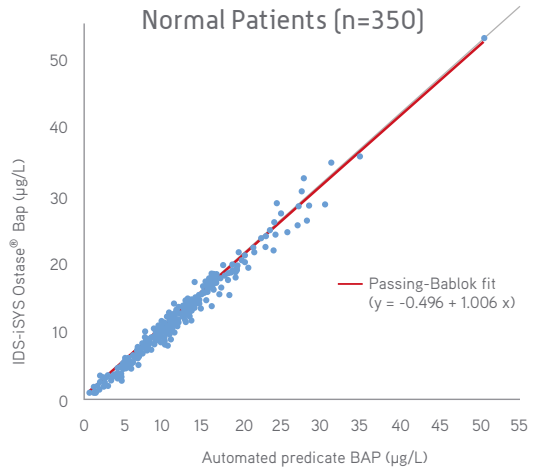
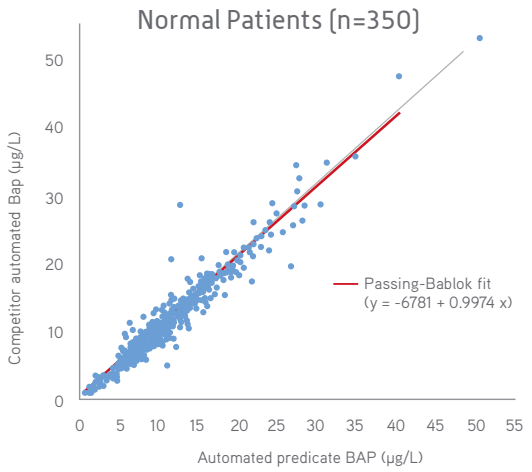
Specifications

Format	Automated spectrophotometric immunoenzymatic assay				
Calibrators	Ready to use – 1 each of 2 concentration levels, 2.5 mL				
Controls	Ready to use – 2 each of 3 concentration levels, 2.5 mL				
Limit of Quantitation	1.0 µg/L				
Dynamic range	1 – 75 µg/L				
Reference Range	**Population**	**Mean (µg/L)**	**SD**	**Median (µg/L)**	**Range (µg/L)**
	Males	11.8	5.9	10.6	5.7 - 32.9
	Pre-menopausal females	11.0	4.5	10.2	4.7 - 27.0
	Post-menopausal females	11.8	6.9	10.4	5.5 - 27.1
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	Sample ID	n	Mean (µg/L)	Within Run	Total
	1	80	9.8	2.0%	9.0%
	2	80	17.5	1.6%	7.7%
	3	80	43.1	1.5%	6.5%
	4	80	61.2	1.3%	6.6%
	5	80	77.4	1.4%	6.6%





Ordering information

Product Name	Description	Code
IDS-iSYS Ostase® BAP	Reagent pack: 100 tests	IS-2800
IDS-iSYS Ostase® BAP Control Set	Control set: 3 levels	IS-2830

Other assays in the Bone Metabolism portfolio

Product Name	Code
IDS-iSYS N-MID® Osteocalcin	IS-2900
IDS-iSYS CTX-I (CrossLaps®)	IS-3000
IDS-iSYS Intact PINP	IS-4000
IDS-iSYS TRAcP 5b (BoneTRAP®)	IS-4100

For more details on our products visit www.idsplc.com

References

1. Epstein S. Serum and urinary markers of bone remodeling: assessment of bone turnover. Endocrine Reviews 9:437-448, 1988.
2. Whyte MP. Alkaline phosphatase and the measurement of bone formation, Clinical Disorders of Bone and Mineral Metabolism. Potts JT and Frame B, eds., pp. 120-125, 1983.
3. Garnero P and Delmas P. Assessment of the serum levels of bone alkaline phosphatase with a new immunoradiometric assay in patients with metabolic bone disease. J Clin Endocrin Metab 77:1046-1053, 1993.
4. Cooper EH, Whelan P, and Purves D. Bone alkaline phosphatase and prostate-specific antigen in the monitoring of prostate cancer. The Prostate 25:236-242, 1994.
5. Van Straalen JP, Sanders E, Prummel MF, and Sanders GTB. Bone alkaline phosphatase as indicator of bone formation. Clin Chim Acta 201:27-33, 1991.
6. Merkow RL and Lane JM. Metabolic bone disease and Paget's disease in the elderly: II. Paget's Disease. Clin Rheum Dis 12:70, 1986.

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