



## Fully Automated Ostase®+ BAP

An automated assay for the quantitative determination of bone specific alkaline phosphatase (BAP) in human serum and heparin plasma. The assay is intended to be used as an aid in the management of postmenopausal osteoporosis and Paget’s disease in conjunction with other clinical and laboratory data.

A consensus group from the International Osteoporosis Foundation (IOF) recommends the use of bone turnover markers for monitoring of anti-resorptive agents and prediction of fracture risk in postmenopausal osteoporosis<sup>1</sup>. The Canadian Consensus Conference on Osteoporosis indicated that bone turnover markers can be used to rapidly assess adherence and effectiveness of pharmacological interventions; Bone Mineral Density (BMD) should not be viewed as the only indicator for management success because therapy may or may not be associated with significant increases in BMD<sup>2</sup>. Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention and Treatment of CKD-MBD guidelines suggests that BAP is a marker to evaluate bone disease because markedly high or low values predict underlying bone turnover<sup>3</sup>.

### Features and Benefits

- Ability to combine the bone turnover markers with the established IDS-iSYS 25-Hydroxy Vitamin D – aiding management of osteoporosis and other metabolic bone diseases.
- 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.

### Specifications

Format	Automated magnetic particle immunoenzymatic						
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 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 to 32.9		
	Premenopausal Females	11.0	4.5	10.2	4.7 to 27.0		
	Postmenopausal Females	11.8	6.9	10.4	5.5 to 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 heparin and sodium heparin)						
Reagent Stability	The IDS-iSYS Ostase®+ BAP reagent cartridge may be stored on-board the IDS-iSYS System for a maximum of 14 days, and for 21 days at 2-8°C.						
Calibration Stability	The calibration of IDS-iSYS Ostase®+ BAP assay is stable for a maximum of 14 days						
Time to 1 <sup>st</sup> Result	43 minutes						
Precision*	Sample ID	N	Mean (µg/mL)	Within Run SD	%CV	Total** SD	%CV
	1	80	9.8	0.2	2.0	0.9	9.0
	2	80	43.1	0.6	1.5	2.8	6.5
	3	80	77.4	1.1	1.4	5.1	6.6

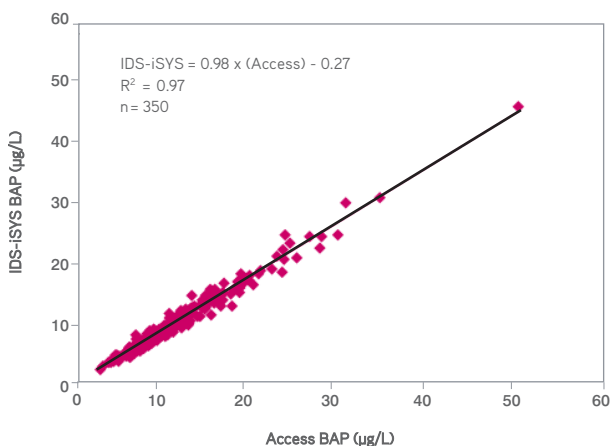
\* Representative data; results in individual laboratories may vary from these data.

\*\* Total is an accumulation of within run, between run and between day.

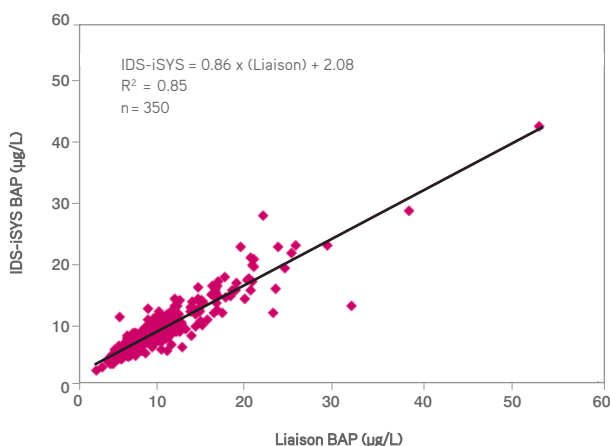
+ Ostase® is a registered trademark of Hybritech Incorporated, a subsidiary of Beckman Coulter, Inc.

# Method Comparison

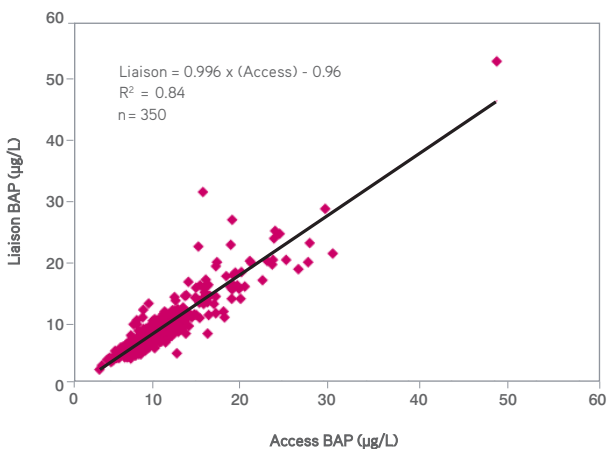
## IDS-iSYS vs. Access BAP



## IDS-iSYS vs. Liaison BAP



## Liaison vs. Access BAP



350 samples (3.6 – 50.3 µg/L) were assessed in three fully automated BAP methods by a clinical laboratory following CLSI EP-9A2, “Method Comparison and Bias Estimation Using Patient Samples”. Linear regression analysis was performed on the comparative data:

$$\text{IDS-iSYS} = 0.98 \times (\text{Access}) - 0.27; R^2 = 0.97$$

$$\text{IDS-iSYS} = 0.86 \times (\text{Liaison}) + 2.08; R^2 = 0.85$$

$$\text{Liaison} = 0.996 \times (\text{Access}) - 0.96; R^2 = 0.84$$

# Ordering Information

Product Name	Description	Code
IDS-iSYS Ostase <sup>®</sup> BAP	Reagent Pack: 100 tests	IS-2800
IDS-iSYS Ostase <sup>®</sup> BAP	Control Set: 3 levels (2 bottles per level, 2.5 mL each bottle)	IS-2830

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# References

1. *Osteoporos Int* 2000; 11(6):S2–S17
2. *SoGC Clinical Practice Guideline*. JOGC. 2006; 172: S95–S112
3. [www.kdigo.org/clinical\\_practice\\_guidelines/kdigo\\_guideline\\_for\\_ckd-mbd.php](http://www.kdigo.org/clinical_practice_guidelines/kdigo_guideline_for_ckd-mbd.php)