Assay information

Automated Kit Reagents

Product Name	Product Code	Sample type / volume	In-use stability / calibration frequency
IDS-iSYS Ostase® BAP	IS-2800	Serum, plasma / 50 µL	21 days / 14 days
IDS-iSYS N-MID® Osteocalcin	IS-2900	Serum, plasma / 50 µL	28 days / 10 days
IDS-iSYS CTX-I (CrossLaps®)	IS-3000	Serum, plasma / 45 µL	28 days / 14 days
IDS Beta CrossLaps® (CTX-I)	IS-3000N	Serum, plasma / 90 µL	4 weeks / 28 days
IDS-iSYS Intact PINP	IS-4000	Serum, plasma / 20 µL	28 days / 3 days
IDS-iSYS TRAcP 5b (BoneTRAP®)	IS-4100	Serum, plasma / 70 µL	28 days / 21 days

Automated Calibrator and Control Sets

Product Name	Product Code	Product Format	In-use Stability
IDS-iSYS Ostase® BAP Control	IS-2830	3 levels, 2 vials each, 2.5 mL	Until expiry date
IDS-iSYS N-MID® Osteocalcin Control	IS-2930	3 levels, 4 vials each, 1 mL	21 days*
IDS-iSYS CTX-I (CrossLaps®) Control	IS-3030	3 levels, 2 vials each, 2.5 mL	Until expiry date
IDS Beta CrossLaps® (CTX-I) Calibrator	IS-3020N	6 levels, 1 vial each, 2 mL	17 weeks
IDS Beta CrossLaps® (CTX-I) Control	IS-3030N	2 levels, 2 vials each, 2.5 mL	17 weeks
IDS-iSYS Intact PINP Control	IS-4030	3 levels, 2 vials each, 1 mL	14 days*
IDS-iSYS TRAcP 5b (BoneTRAP®) Control	IS-4130	3 levels, 3 vials each, 1 mL	8 hours*

*after reconstitution, at -20°C # after reconstitution, at 2 to 8°C

ELISA Kits

Product Name	Product Code	Sample type / volume	In-use stability
Serum CrossLaps® (CTX-I) ELISA	AC-02F1	Serum, plasma / 50 µL	Until expiry date
Urine CrossLaps® (CTX-I) EIA	AC-03F1	Urine / 15 µL	Until expiry date
Alpha CrossLaps® (CTX-I) EIA	AC-04F1	Urine / 25 µL	Until expiry date
Urine BETA CrossLaps® (CTX-I) ELISA	AC-05F1	Urine / 20 µL	Until expiry date
N-MID® Osteocalcin ELISA	AC-11F1	Serum, plasma / 20 µL	Until expiry date
Ostase® BAP EIA	AC-20F1	Serum / 50 µL	Until expiry date
BoneTRAP® (TRAcP 5b) ELISA	SB-TR201A	Serum, plasma / 100 µL	Until expiry date

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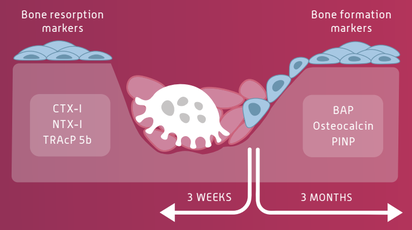
Bone Turnover

Bone turnover, also called bone remodelling, is a dynamic, lifelong process in which old bone is removed (resorption) from the skeleton and new bone (formation) is added. This process is tightly regulated through the action of various systemic hormones (e.g. parathyroid hormone (PTH), vitamin D etc.) and local mediators (e.g. cytokines and growth factors).

During the bone remodelling process, compounds are released either from bone or from the cells involved (osteoblasts and osteoclasts).



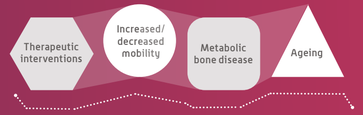
Adapted from Schini M et al, 2023[1].

Normal

In a typical situation, bone resorption and formation are tightly coupled to each other, so that the amount of bone removed is equal to the amount of newly formed bone.

Imbalances

In contrast, ageing, metabolic bone diseases, states of increased or decreased mobility, therapeutic interventions and many other conditions can upset the bone turnover balance.



Bone Turnover Markers (BTMs)

Depending on their involvement in the bone remodelling process, BTMs are categorised into bone formation or resorption markers.

Bone resorption markers are all related to osteoclast resorption of the bone matrix:

Dissolution of the mineralised matrix – tartrate-resistant acid phosphatase 5b (TRAcP 5b)
Degradation of the protein matrix – telopeptides of collagen type I (CTX-I and NTX-I)

Bone formation markers reflect different aspects of osteoblast function and of bone formation:

Deposition of protein matrix – osteocalcin and propeptides of type I collagen (PINP)
Mineralisation of the matrix – bone-specific alkaline phosphatase (BAP)

Paget's Disease

Paget's disease of bone is the second most common metabolic bone disorder. It is a chronic, slowly progressing condition with unusually rapid resorption and disorganised formation. The shape and size of the newly formed bone is typically affected with it being structurally dense but fragile.

Symptoms

- Bone pain
- Bone deformities
- Headache
- Fractures

Commonly affected bones

- Spine
- Pelvis
- Legs
- Skull

Population[2,3]
- Affects males slightly more than females
- Affects individuals of all ethnic and racial groups
- Affects 1-2% of populations
- Rarely diagnosed under 40 years. Affects 3% of those over 60 years (40+ YEARS)

Diagnosis[1]: X-ray; BAP, CTX-I or PINP

Osteomalacia

Osteomalacia is a metabolic bone disorder characterised by altered skeletal mineralisation and weakened bones, predominantly due to vitamin D deficiency[1,7,8]. This deficiency causes abnormal mineralisation of the bone matrix (osteoid) resulting in 'softening' of bones.

Symptoms

- Bone pain
- Pseudofractures of feet and pelvis
- Muscle weakness
- Affects gait / walk

Causes

- Lack of phosphorous
- Liver disorders
- Coeliac disease
- Genetic factors

Diagnosis[7,8]: X-ray; Calcium; Vitamin D; PTH; BAP; CTX-I; PINP; Osteocalcin

Hypophosphatasia

Hypophosphatasia (HPP) is a rare inherited condition resulting from variants to the gene coding for tissue nonspecific alkaline phosphatase (TNSALP)[4]. The condition is characterised by impaired mineralisaton (calcification) of teeth and bones resulting from the deficiency of TNSALP in cells involved in the turnover process[5]. HPP is categorised into 6 clinical forms based on the age when symptoms occur and diagnosis made – Perinatal, prenatal benign, infantile, childhood and adult HPP, and odontohypophosphatasia.

Symptoms

Perinatal
- Bowed limbs
- Chest deformity
- Stillbirth

Children and infants
- Bone malformation
- Failure to thrive
- Early teeth loss

Adults
- Osteomalacia
- Cartilage damage
- Stress fractures common
- Unexplained loss of teeth

Population[4]
- Affects males and females equally
- Incidence between 1 in 100,000 to 300,000[6]
- Prevalence of adult form 1:3100 to 1:508 in EU[6]
- Age at onset indicates clinical form (AT ONSET)

Diagnosis[1,4,6]: X-ray; Alkaline Phosphatase (ALP), BAP, DNA sequencing

Metastatic Bone Disease

Metastatic bone disease is a cancer which originates in an organ or tissue, such as breast, prostate or thyroid, which spreads to bone. It is estimated that up to 50% of cancers that start in organs can metastasise to bone. The tumour can either lead to the destruction of the area of the affected bone or create legions causing weakness or deformity of the affected bone.

Symptoms

- Bone pain
- Fractures
- Anaemia

Incidence of metastasis[9]*

- 73% Breast cancer
- 68% Prostate cancer
- 42% Thyroid cancer

* measured during post mortem

Prospective studies suggest that TRAcP 5b, PINP, BAP and CTX-I levels are significantly higher in patients with metastases than those without[1]. Furthermore, the combination of BAP, PINP and TRAcP 5b has been recommended in the early stages of some cancers for early diagnosis of bone metastasis[10]. However, despite positive associations between BTMs and presence of metastases, their use in clinical practice is limited.

Supporting patient management

- **Comprehensive panel** to support diagnosis and monitoring of metabolic bone diseases
- Measurement in **multiple sample types**
- Full bone turnover menu **supports translational research**

Confidence in results

- **Fast responses** help prevent delays in diagnosis
- **Broad analytical measuring** ranges allow accurate quantification of markers

Simplified workflow and cost effective solutions

- **Ready to use** reagents
- **Random access** of both sample and reagent (CLIA)
- Up to 28 days on-board storage and up to 28 days calibration frequency (CLIA); ELISA open use stability up to kit expiry