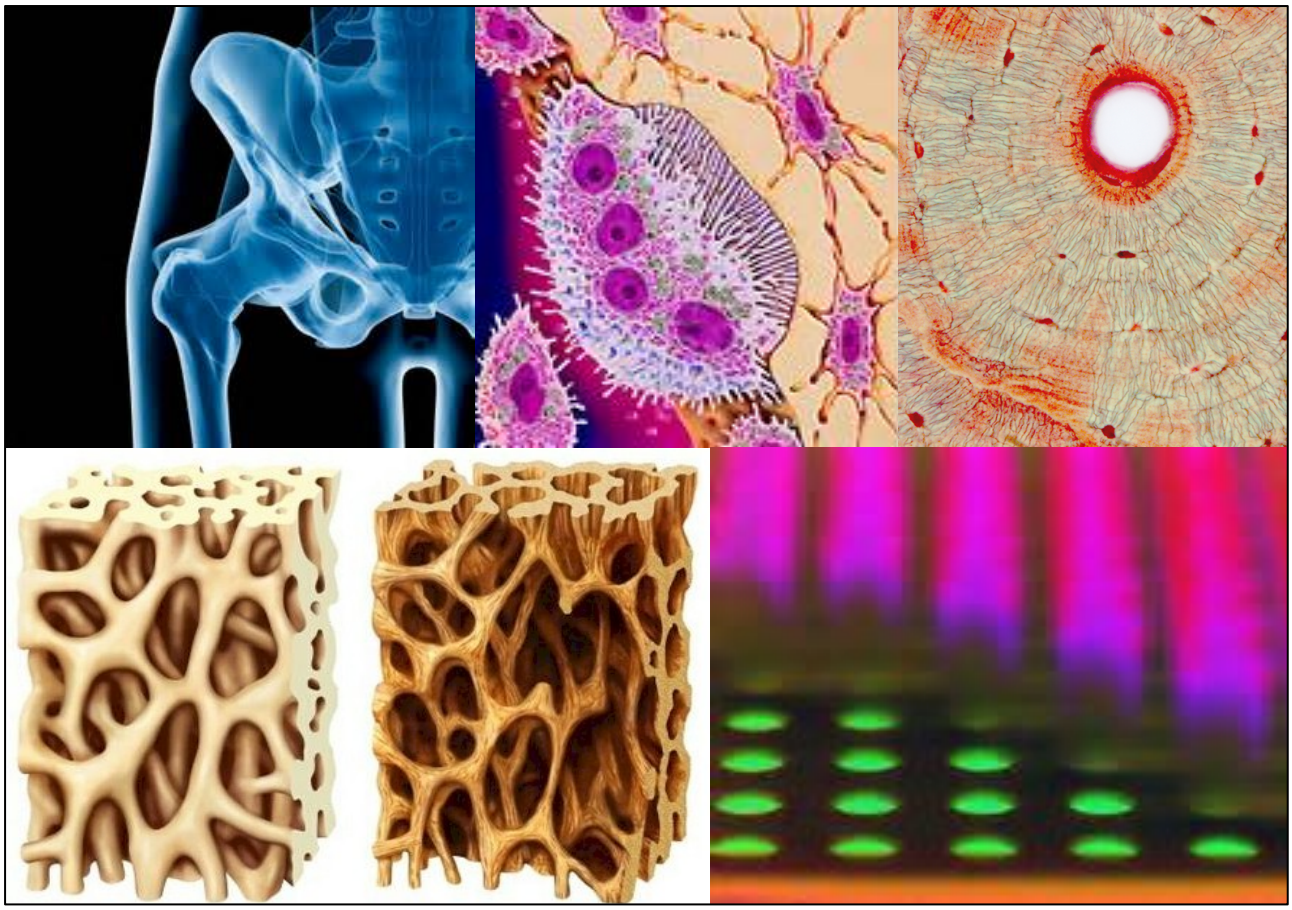
Bone-Remodeling Factor Balance and Osteoporosis Molecular Pattern

- Osteoporosis is the most common type of bone disease worldwide, involving low bone mineral density and increased susceptibility to fracture. More than 200 million people worldwide (30% of women and 20% of men over 50) suffer from osteoporosis or osteoporotic fractures.
- Osteoporosis is associated with postmenopausal period, but it is also a major comorbidity in obesity, type 2 diabetes mellitus, chronic obstructive pulmonary disease, systemic lupus erythematosus and has strong genetic determination (60% heritability), and over 100 genes and proteins are underlying osteoporosis and influencing the response to anti-osteoporotic therapy.



- Medications available to treat osteoporosis and reduce the risk of fracture fall into two basic categories: Antiresorptive drugs, slowing resorption or breaking down part of the remodeling cycle; and Anabolics, stimulating formation part of the remodeling process. Their result is stronger bone and reduced likelihood of having fragility fractures. However, there is no best medication for everyone and the one that works for a particular patient depends on many factors, including the specific expression pattern of bone-remodeling factors.

- We customize an effective assessment of osteoporosis and fracture risk, and monitoring of anti-osteoporosis treatment efficacy, supported by a Laboratory Diagnostic Test (LDT) using a protein expression profiling method based on a multiplex fully automated, protein array chip system.
- Our LDT determines the blood level of a broad number of bone-turnover and inflammatory biomarkers including:
    - Sclerostin (SOST)
    - Osteocalcin (OSC)
    - Osteoprotegerin (OPG)
    - Secreted frizzled related protein 1 (SFRP-1)
    - Dickkopf 1 (DKK-1)
    - IGF-1
    - Osteopontin (OPN)
    - C-telopeptide type I collagen (β-CTX)
    - N-terminal procollagen prepeptide (P1NP)
    - Receptor activator nuclear κB ligand (RANKL)
    - Tumor necrosis factor alpha (TNFa)
    - C-reactive protein (hsCRP)
    - Vitamin D3 (1,25-dihydroxycholecalciferol)
    - Parathyroid hormone (PTH)

- **Offered LDT may help:**
    - **Molecular sub-typing of osteoporosis and treatment guidance.**
    - **Monitoring of adherence to osteoporosis treatment.**
    - **Monitoring of patients taking a pause from bisphosphonate treatment.**
    - **Monitoring of response to bisphosphonate treatment withdrawal.**
    - **Providing a companion diagnosis for new target-oriented osteoporosis therapies.**

- This test was developed, and its clinical performance features determined by PBM. It has not been cleared or approved by the FDA. It should not be regarded as investigational or for research.
- Final diagnosis and optimal patient management are the responsibility of the referring physician or health care provider.