Fact Sheet – osteomiR™ test

1. Who is the target audience for osteomiR?
- Osteologists, Endocrinologists, Gynecologists, Orthopedists
- Doctors who are dealing with osteoporosis in addition to their medical specialty
- Everyone else in a hospital who needs information about the bone quality and fracture risk of their patients in order to improve management.
- Scientific groups dealing with bone quality and diseases of the bone

2. What is osteomiR?
The osteomiR™ test enables quantitative analysis of 19 microRNAs in human serum samples. These microRNAs are novel bone biomarkers, that can inform about the fracture risk of a patient. This is achieved through an AI-based algorithm that converts microRNA abundance into a fracture risk score. The 19 individual biomarkers are surrogates of the factors that influence fracture-risk, such as bone turnover, histomorphometry, muscle strength, inflammation, kidney function etc.

3. For which patients is the osteomiR™ test suitable?
- Postmenopausal women
- Type-2 diabetic women
- Exploratory: breast cancer patients undergoing aromatase inhibitor therapy

4. What exactly is the osteomiR™ test kit?
The osteomiR™ test is an RT-qPCR assay, which enables quantitative analysis of circulating microRNAs in human serum samples.

Each kit comprises the following components:
1. Serum RNA extraction kit containing all reagents, spin columns and collection tubes to extract RNA from serum samples required for osteomiR™;
2. The RT-qPCR chemistry comprising spike-in controls, all reagents for cDNA synthesis and the miGreen PCR Mix;
3. Primer-coated qPCR plates in 96 well or 384 well format

8. How many samples can we measure with one osteomiR™ kit?

One kit is suitable for analysis of up to 48 samples.

9. Does the osteomiR™ kit require a specific instrument or can it be run with any qPCR instrument?
A wide range of qPCR cyclers equipped with 96 well/384 well-blocks are compatible with osteomiR™ plates. On our homepage, you find a list of compatible qPCR cyclers, for which we can have suitable plates manufactured.

10. Advantages of osteomiR™ kit?

- A blood-based biomarker to assess fracture-risk; requires only patients' serum and no additional clinical data.
- AI-based algorithm integrates microRNA levels that reflect several fracture-risk factors into an easily interpretable risk score.
- The only test intended to provide information about the 3-year fracture-risk of an individual.

11. Correlations of osteomiR™ to other fracture-risk assessments?

osteomiR™ shows better performance for the identification of patients with high risk of fracture (up to 36 months) than BMD or FRAX.

12. Sample requirements for osteomiR™ kit

- Sample type: human serum. However, the kit has been shown to enable proper detection also in EDTA-plasma. (Conditions during serum or plasma processing might affect the detection of microRNAs using qPCR. Therefore, we strongly recommend to standardize protocols for pre-analytical processing and serum collection.)
- Sample volume: 200 µl
- Sample stability:
  o Blood can be stored 6 hours at room temperature before centrifugation.
  o After centrifugation plasma should be frozen if the analysis is not performed right away. -20°C for up to 4 weeks. -80°C for long-term storage.
- Shipment: frozen shipment on dry ice is required