

Don't see anything yet? We detect osteoporosis.

Information for physicians

The new
scientific lab
test

Our research and funding partners:



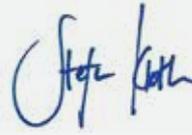
Evidence based.
Medically proven.

osteolabs
early detection of osteoporosis

Dear Doctor,

Osteoporosis should be diagnosed as early as possible. This is the only way to offer your patients the opportunity to live symptom-free with this disease. There should also be a reliable method of measurement to accompany therapy and demonstrate the success of any treatment. In this brochure we want to bring you up to speed with the latest science in relation to osteoporosis diagnostic procedures. We would also like to suggest that you complement proven methods such as the DXA diagnostic procedure with the innovative analytical method from osteolabs.

We invite you to familiarise yourself with what the latest technology is capable of and to tackle osteoporosis in a highly successful manner as a partner of osteolabs.



Yours sincerely,
Dr. Stefan Kloth, managing director of osteolabs GmbH



THE TEST

Early detection of osteoporosis with osteolabs and accompany therapies safely

osteolabs is the ideal companion for the therapy of osteoporosis. The procedure provides exact measured values for determining bone density. Changes can be identified and evaluated objectively and scientifically. Used on a regular basis, you as the treating physician will receive an overview of all relevant values in the context of osteoporosis therapy. As the procedure measures values in the blood and/or urine, there is no radiation exposure. Thanks to osteolabs, doctors can identify even the smallest changes in the bone structure.

The laboratory test complements the previous DXA diagnostic procedure (X-ray). There is no further radiation exposure for patients. After a short period of time (days to weeks), the effectiveness of therapy can be measured. There is no significant additional work in the doctor's office, as blood and urine are taken in the laboratory. The test is the only one of its kind in the world, evidence-based and medically proven.

Each test also provides an assessment of renal function (creatinine, eGFR, cystatin C) and vitamin D levels.

Procedure - this is how the test works:

-  Order a free test kit
-  Take a blood and urine sample from the patient
-  Submit the samples to the laboratory
-  Receive report from the laboratory
-  Discuss results with the patient



The sampling kit includes:

- Urine cup
- Urine monovette, Luer 10 ml, 102 x 15 mm
- S-monovette 7.5 ml serum with clot activator
- 2 protective vessels 126 x 30 mm with suction insert for monovette
- Screw cap for protective vessel yellow
- Screw cap for protective vessel red
- Return envelope

Calcium biomarkers are the key to new possibilities in osteoporosis therapy

This method was developed in a 17-week study by NASA (J. Skulan et al 2007). Building on this, clinical studies were carried out in cooperation with University Medical Centre Schleswig-Holstein (UKSH) and the GEOMAR Helmholtz Centre. With a sensitivity of 100 %, all previously detected cases of osteoporosis were identified by using calcium isotope markers (CIM). In addition, thanks to the newly developed method, other affected women could also be identified.

Calcium (Ca⁺⁺) occurs in food in different heavy isotopes, e.g. ⁴²Ca or ⁴⁴Ca vor. Light Ca isotope undergo chemical reactions faster than heavy ones and accumulate at the end of the process in bones.

Because light Ca isotopes react more quickly, mostly light Ca isotopes (⁴²Ca) are incorporated during bone formation. If an increased level of light Ca isotopes are incorporated, a greater quantity of heavy Ca isotopes (⁴⁴Ca) remain in the blood/urine. During the breakdown of bone substance, the reverse occurs. There are increased light Ca isotopes from bones in the blood/urine.

The measurement method of osteolabs is a world first, as it now makes it possible to diagnose osteoporosis at the onset of postmenopause. The patient receives a quick and reliable certainty about a possible osteoporosis - even long before a X-ray test is carried out.

Advantages for patients - quick, secure assurance



The diagnosis of osteoporosis can be made before larger quantities of bone substance have been lost.



After a short period of time (days to weeks), the effectiveness of treatment can be measured.



No radiation exposure for the patient, as no X-rays are used, and all methods used are non-radioactive.

THE RESULT

Test result and therapy discussion

After receiving the test result, discuss further treatment options with the patient. This is what a real result looks like, for example: The two scales on the left show that the Ca-isotope ratios in both serum and urine are significantly lowered, suggesting the presence of osteoporosis. Graphically, this can also be seen by the fact that the arrows point to the red area. In addition, any findings of osteolabs are evaluated, validated and possibly measures are recommended by a laboratory physician.

"At the University Medical Centre Schleswig-Holstein (UKSH) this novel osteoporosis test was clinically validated and published by me as co-author in the journal "Bone Reports 10 (2019)." We use this early test, which is based on a calcium isotope fractionation by mass spectrometry, here at the UKSH since 2019."



Dr. med. Michael Müller,
Senior Physician of the Clinic for
Orthopaedics and Trauma Surgery,
University Medical Centre Schleswig-
Holstein, Germany

Example: This is how a typical finding looks like.



Patient: Eingang:	Ausgang:	Geb.-Datum: Ihre Nummer:	Status: Endbefund Bef.-Nr.: 06810125
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Calcium Isotopenverhältnis zur Osteoporosediagnostik

Bestimmung	Resultat	Referenz	Einheit	Calcium Isotopenverhältnis		
Serum:						
Kreatinin	0,59	- 0,60 - 1,00	mg/dl			
eGFR DMP (CKD-EPI)	98	> 60	ml/min.			
Cystatin C	0,77	0,53 - 1,05	mg/l			
GFR Cystatin C	99	>60	ml/min.			
Calcium	2,48	2,20 - 2,65	mmol/l			
Delta 44/42 Ca Serum	-1,41	-! >-0,85	Promill			
25-OH-Vitamin D	121	>50 (>75)	nmol/l			
Urin						
Kreatinin i.U.	23,9	- 60 - 300	mg/dl			
Delta 44/42 Ca Urin	-0,42	-! >0,22	Promill			
Calcium i.U.	3,05	<5,1	mmol/l			
f-Wert renale Reabs.	96,4		%			

Beurteilung:

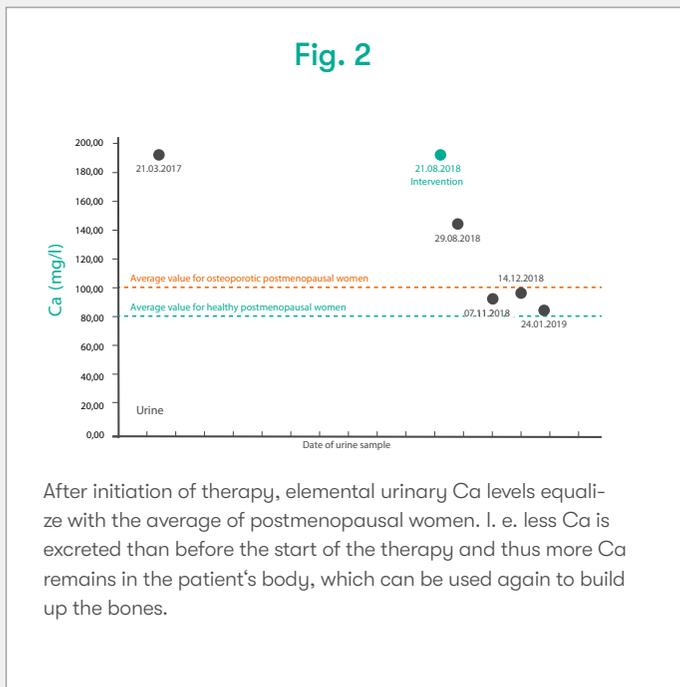
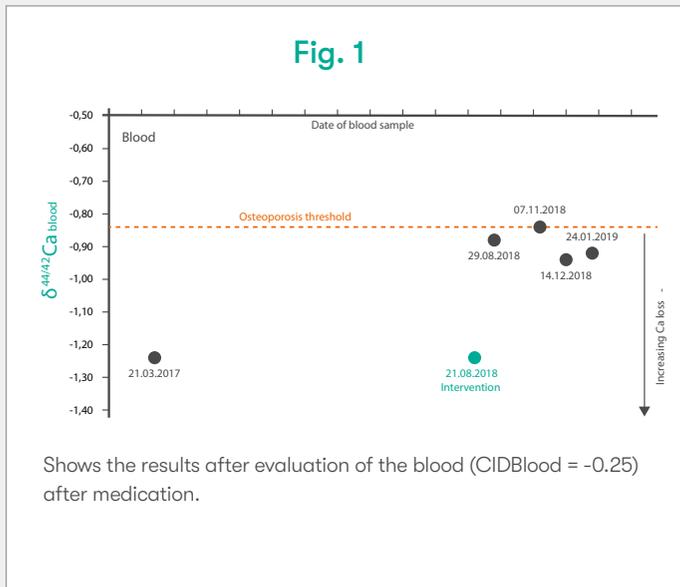
Anamnestisch: Kurzdarmsyndrom, Z.n. Th12-Fraktur in den letzten zwei Jahren; Klimakterium 2007; Therapie: Prednisolon, Sulfasalazin, Candesartan, Verapamil

Delta Ca 44/42 in Blut und Urin erniedrigt. Dieses zeigt einen deutlich verstärkten Abbau von Calcium bzw. ein osteoporotisches Geschehen.

Zwecks Therapiekontrolle sind Messungen ca. 1-2 Wochen nach Einleitung sinnvoll. Zusätzlich Kontrollen in ein bis zwei Jahren sowie Knochendichtemessung im Verlauf empfohlen.

CASE STUDY

Treatment example of a German gynaecologist. osteolabs in practice.



Gynaecologist Bettina Wihlfahrt from Germany is using the osteolabs test procedure since a certain time. She reports on a real case from her everyday practice. The patient has agreed to the description of her case. The first osteolabs test was carried out on 31/03/2017.

In Fig. 1 you can see the results of the osteolabs blood test (black dot with the label 21/03/2017). The black dot represents an osteolabs blood value of -1.23, indicating severe osteoporosis. This value corresponds to a DXA-T value of well below -2.5.

The dashed orange line represents the threshold for osteoporosis, i.e. measurement points below this line indicate osteoporosis (increasing calcium loss).

As considered appropriate by the doctor, the patient was administered Estramon Conti 30/95 (hormone compound) as from 21/08/2018 (green dot labelled intervention). Just 8 days after the intervention (black dot labelled 29/08/2018), the osteolabs blood measurement passes the threshold value again (orange dotted line), i.e. it can be seen that the therapy is taking effect and calcium loss has been significantly reduced.

This reduction in calcium loss can also be seen in Fig. 2: This shows the elemental calcium in urine over time. It can be seen that after the intervention, the absolute amount of calcium in the urine (measured in mg/l) decreases, showing that more calcium is now remaining in the body and consequently that less calcium is being excreted in the urine.

Success in practice:

Thanks to osteolabs, Dr. Wihlfahrt could show that the Calcium isotopes ratios (⁴⁴/₄₂Ca) of her patient have risen to the age-appropriate average for healthy postmenopausal women just eight days after intervention. Dr. Wihlfahrt's view: "My patient was able to return to her previous job. My focus is always on the patient, including in the selection of the test method. In this case the osteolabs test offered good options both before and during treatment: I could assess after just a very brief time which treatment was the right one for my patient. And I could control the medication, for the benefit of my patient."

"The test offers good possibilities before and during therapy - that's why I recommend it to my patients."



Bettina Wihlfahrt,
Gynaecologist, Germany

RECOMMENDATION

Include this early test in your daily practice routine

- ✔ This test offers specialists the opportunity to reliably document treatment progress. The test makes treatment results transparent for patients and demonstrates his value.
- ✔ You offer your patients a method that provides a very safe test for osteoporosis. This is a strong argument for patients to visit your practice.
- ✔ Privately-insured patients in certain European countries can have the costs reimbursed by their insurance company (it is advisable to obtain a prior agreement to provide cover).
- ✔ The test is an innovative breakthrough. Be one of the first doctors in your area to offer it to patients.

Offer your patients the OsteoTest now! Let yourself be listed on our website as a proven expert and user of the new procedure for the early detection and treatment of osteoporosis. Your patients will also benefit from this cooperation, as the new procedure can be used to predict possible osteoporotic fractures in good time, see the following study.

"I usually apply this test to every woman over 50 to allow early detection of the disease."

Gabriele Lorentz,
GP, Germany



STUDY

Comparison DXA method vs. OsteoTest | med

100 women over 70 years of age were examined for osteoporosis by X-ray (DXA) and by OsteoTest | med.

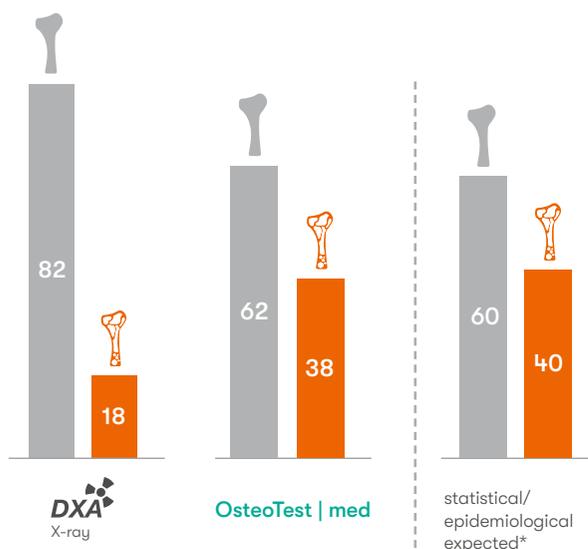
Diagnosis 2016

Legend:

- non-pathological/
non-osteoporotic
- pathological/
osteoporotic

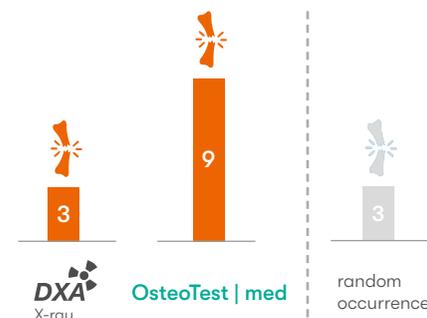
*For women over 70, in Cranney, A., et al. (2007). "Low bone mineral density and fracture burden in postmenopausal women." Canadian Medical Association Journal 177(6): 575-580.

Quelle: Study "Frakturaspekt_GEO-Osteo-2016", n=100 postmenopausal women, NCT02967978, Clinical Research Centre Kiel GmbH



Fractures after 2 years: 2018

98 of the 100 female subjects (2 had died) were asked about fractures in the last 2 years. In total, 12 fractures occurred, 9 of which were due to osteoporosis. The OsteoTest | med had previously diagnosed all 9 affected probands as osteoporosis risk patients.



Billable services

Before testing

GOÄ 1: Advice also by telephone (2. 3 times the rate = 10.72€). If there is a risk of osteoporosis, it is to provide information and advice. Thereby – also to an early stage – the diagnostic possibilities including of the osteolabs process.

possibly GOÄ 857: Application and evaluation of orienting test procedures, e. g. the osteoporosis questionnaire test (1. 8-times the rate = 12.17€).

After testing

possibly GOÄ 60: Consultation between two or more doctors entitled to liquidation, (2. 3 times the rate = 16.09€) chargeable when the test results are discussed (also by telephone) with the laboratory doctor.

if the result is positive: GOÄ 34: Discussion (duration at least: 20 minutes) of the effects of a disease on the way of life in direct connection with the detection or significant worsening of a long-term life-changing or life-threatening disease (2. 3 times the rate = 40.23€).

if the result is negative: GOÄ 1: Counselling also by telephone (2.3 times the rate = 10.72€)

When marine researchers and medical professionals work closely together

osteolabs GmbH is an innovative company in the field of medical diagnostics and won the "Germany - Land of Ideas" award in 2017 for its outstanding research achievements. The development of the new and radiation-free diagnostic procedure was funded by GEOMAR Helmholtz Centre for Ocean Research Kiel and the Helmholtz Association Berlin.

The clinically tested diagnostic procedure is a world first, as it can detect osteoporosis at a very early stage and control or verify osteoporosis therapies. The method has been internationally patented under WO 2020/043771 A1.

EVIDENCE BASED

Medically tested and confirmed test procedure

In cooperation with the University Medical Centre Schleswig-Holstein, the GEOMAR Helmholtz Centre, Prof. Eisenhauer and osteolabs GmbH in Kiel and the company CRC Kiel, several clinical studies were carried out.

- Maximum transparency thanks to studies and publications
- 2019: Bone Reports 10 (2019) 100200: Calcium isotope ratios in blood and urine: A new biomarker for the diagnosis of osteoporosis.
- 2016: Isotopes in Environmental and Health Studies 52 (2016) 1-16: Biological fractionation of stable Ca isotopes in Göttingen minipigs as a physiological model for Ca homeostasis in humans.
- 2010: Bone 46 (2010) 889: A pilot study on the use of natural calcium isotope ($^{44}\text{Ca}/^{40}\text{Ca}$) fractionation in urine as a proxy for the human body calcium balance.

Evidence based.
Medically proven.



"Sensational. osteolabs is a role model for a successful start-up."

Dr. Bernd Buchholz,
Minister for Economic Affairs of Schleswig-Holstein, Germany



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