



ALPHA CrossLaps® ELISA

FOR RESEARCH USE ONLY

High-Turnover Bone Resorption Marker For Clinical Trials and Patient Monitoring

Bone metastases

- Early Identification of Bone Metastases
- Monitoring of Anti-Resorptive Treatment

Assessment of patients with pathological high bone turnover

- with Metabolic Bone Disease, e.g. Paget's Disease
- with Bone Cancer, e.g. Multiple Myeloma

The ALPHA CrossLaps® ELISA is used for quantitative assessment of bone resorption. The assay detects non-isomerized C-telopeptide fragments of collagen type I (CTX-I) generated during osteoclastic bone resorption.

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Serum CrossLaps®
ELISA

Urine CartiLaps®
ELISA

RatLaps™
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Pre-Clinical CartiLaps®
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N-MID® Osteocalcin
ELISA

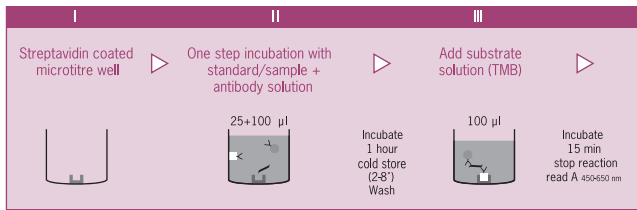
CrossLaps® for Culture
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Rat-MID™ Osteocalcin
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Urine CrossLaps®
ELISA

ALPHA CrossLaps® ELISA

ENZYME IMMUNOASSAY FOR QUANTITATIVE ASSESSMENT OF PATHOLOGICAL HIGH BONE RESORPTION



Performance Characteristics

Method:	• Sandwich ELISA
Format:	• 96-well microplate with reagents sufficient to test 40 samples in duplicate
Detection limit:	• 0.2 ng/mL
Analyte:	• non-isomerized sequence (EKAHDGGR) specific for a part of the C-terminal telopeptide α 1 chain of type I collagen (CTX)
Specimen:	• Urine
Specimen volume:	• 25 μ L
Precision CV intraassay:	• <5%
Precision CV interassay:	• <6%
Species reactivity:	• Human
Assay time:	• Approx. 1,5 hours

The ALPHA CrossLaps® ELISA kit is for *in vitro* use only.
Product number #5CRL4000

Sampling

Collection of the second morning void after overnight fasting. Freeze samples within 3 hours after collection (<-18°C).

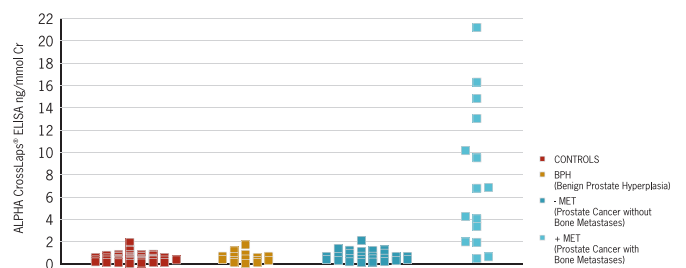
Do not add HCl to urine samples.

Expected values	Mean (95% CI)
Premenopausal women	0.65 ng/mmol Cr (0.18-2.42)
Postmenopausal women	0.30 ng/mmol Cr (0.10-0.94)
Males	0.45 ng/mmol Cr (0.15-1.31)

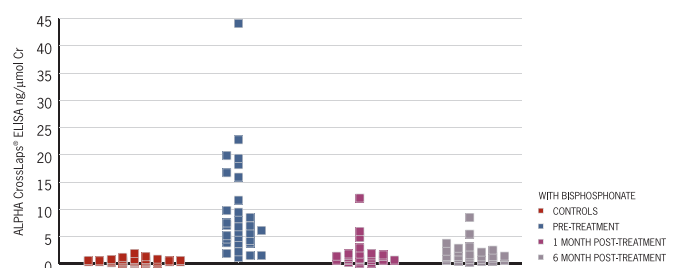
Assay Procedure

1. Prior to use, prepare and equilibrate all solutions to room temperature.
2. Pre-dilute urine samples 1+3 in Standard A.
3. Prepare **Antibody Solution** immediately before use.
4. Pipette 25 μ L of either **Standards**, **Control**, or unknown samples into appropriate wells followed by 100 μ L of the **Antibody Solution**. Cover the immunostrips with sealing tape and incubate for 60 \pm 5 minutes at 2 - 8°C.
5. Wash the immunostrips 5 times manually with **Washing Buffer** diluted 1+50 in distilled water.
6. Pipette 100 μ L of the **Substrate Solution** into each well and incubate for 15 \pm 2 minutes at room temperature (18-22°C) in the dark. Use sealing tape.
7. Pipette 100 μ L of the **Stopping Solution** into each well.
8. Measure the absorbance at 450 nm with 650 nm reference within two hours.

Assessment of prostate cancer patients with bone metastases



Paget's disease patients monitored with ALPHA CrossLaps® ELISA



LITERATURE: **1.** CLOOS ET AL. *BIOCHEM J* 345:473-480 (2000). **2.** CLOOS ET AL. *BREAST CANCER RES* 5:R103-R109 (2003). **3.** DE LA PIEDRA ET AL. *OSTEOPOROS INT* 10:480-486 (1999). **4.** DELMAS ET AL. *J BONE MINER RES* 14:66-69 (1999). **5.** FLEDELIUS ET AL. *J BIOL CHEM* 272:9755-9763 (1997). **6.** GARNERO ET AL. *BR J CANCER* 82:858-864 (2000). **7.** GARNERO ET AL. *J BONE MINER RES* 12:1407-1415 (1997). **8.** GARNERO ET AL. *ARTHRITIS RHEUM* 41:354-360 (1998). **9.** GARNERO ET AL. *J BONE MINER RES* 17:826-833 (2002). **10.** HOSHINO ET AL. *OSTEOPOROS INT* 9:405-409 (1999). **11.** KAWANA ET AL. *CLIN CHEM ACTA* 316:109-115 (2002). **12.** PERIS ET AL. *J BONE MINER METAB* 20:116-120 (2002). **13.** PERIS ET AL. *BONE* 25:349-353 (1999). **14.** REGINSTER ET AL. *CALCIF TISSUE* 69:130-137 (2001). **15.** TAKAHASHI ET AL. *CLIN CHIM ACTA* 279:69-76 (1999).

all the way

FROM RESEARCH TO PATIENT MONITORING