



# Serum CrossLaps® ELISA

Cleared by FDA

## Bone Resorption Marker (CTX-I) For Clinical Trials and Patient Monitoring

### Postmenopausal osteoporosis

- Prediction of long-term skeletal response to anti-resorptive therapies, e.g. HRT, bisphosphonates
- Patient motivation and compliance

### Assessment of bone resorption in patients

- With metabolic bone disease, e.g. hyperparathyroidism, Paget's disease, osteodystrophy
- Receiving prolonged glucocorticoid therapy

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

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Serum CrossLaps®  
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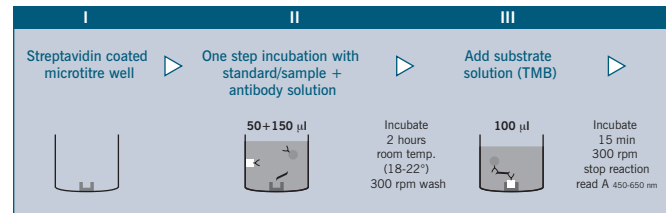
CrossLaps® for Culture  
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## Serum CrossLaps® ELISA

### ENZYME IMMUNOASSAY FOR QUANTITATIVE ASSESSMENT OF BONE RESORPTION



#### Performance Characteristics

Method:	• Sandwich ELISA
Format:	• 96-well microplate with reagents sufficient to test 40 samples in duplicate
Detection limit:	• 0.010 ng/mL
Analyte:	• $\beta$ -isomerized sequence (EKADHGGR) specific for a part of the C-terminal telopeptide $\alpha$ 1 chain of type I collagen (CTX-I)
Specimen:	• Serum or plasma
Specimen volume:	• 50 $\mu$ L
Precision CV intraassay:	• < 6%
Precision CV interassay:	• < 10%
Species Reactivity:	• Human, bovine, horse, sheep, goat, pig, dog, elephant, chicken
Shelf life:	• 12 months
Assay time:	• Approx. 3 hours

#### Sampling

Collect blood samples after overnight fasting and separate serum or plasma within 3 hours. For prolonged storage samples should be frozen (<-18°C).

#### Analyte Stability

	Serum	Plasma
at +4°C	3 days	>60 days
< -18°C	>36 months	>36 months

The Serum CrossLaps® ELISA kit is for *in vitro* only.

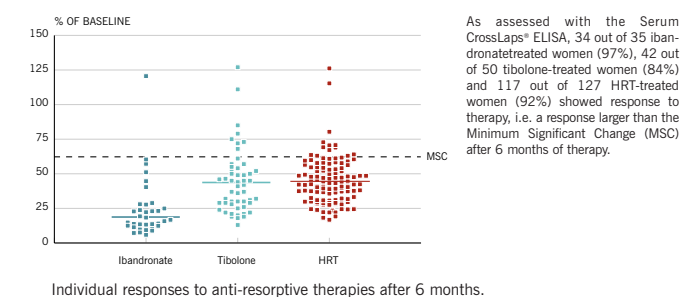
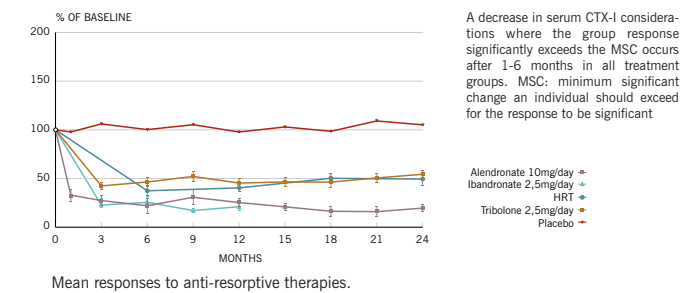
Product number #4CRL4000.

#### Assay Procedure

1. Prepare **Antibody Solution** maximum 30 minutes before starting the assay. Prior to use equilibrate all solutions to room temperature. **Perform the assay at 18-22°C.**
2. Pipette 50  $\mu$ L of either **Standards**, **Control**, or unknown samples into appropriate wells followed by 150  $\mu$ L of the **Antibody Solution**. Cover the immunostrips with sealing tape and incubate for 120 $\pm$ 5 minutes at 18-22°C on a microplate mixing apparatus at 300 rpm.
3. Wash the immunostrips 5 times with **Washing Buffer** diluted 1+50 in distilled water.
4. Pipette 100  $\mu$ L of the **Substrate Solution** into each well and incubate for 15 $\pm$ 2 minutes at 18-22°C in the dark on the mixing apparatus (300 rpm). Use sealing tape.
5. Pipette 100  $\mu$ L of the **Stopping Solution** into each well.
6. Measure the absorbance at 450 nm with 650 nm as reference within two hours.

Expected values	Mean $\pm$ SD
Premenopausal women	0.321 $\pm$ 0.155 ng/ml
Postmenopausal women	0.506 $\pm$ 0.255 ng/ml
Males	0.332 $\pm$ 0.190 ng/ml

#### Antiresorptive effects monitored by Serum CrossLaps® ELISA



LITERATURE: 1. BJARNASON & CHRISTIANSEN BONE 26, 561-569 (2000). 2. BUCLIN ET AL. J BONE MINER RES 17, 1478-1485 (2002). 3. CHRISTGAU ET AL. BONE 26, 505-511 (2000). 4. DELMAS OSTEOPOROS INT 11, S66-S76 (2000). 5. DELMAS ET AL. BONE 26, 553-560 (2000). 6. FINK ET AL. OSTEOPOROS INT 11, 295-303 (2000). 7. RAVN ET AL. BONE 30, 320-324 (2002). 8. RAVN ET AL. BONE 24, 237-244 (1997). 9. REGINSTER ET AL. CALCIF TISSUE INT 69, 130-137 (2001). 10. ROSEN ET AL. CALCIF TISSUE INT 66, 100-103 (2000).

ISO 9001 certified

all the way

FROM RESEARCH TO PATIENT MONITORING

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