

The Urine CartiLaps® (CTX-II) EIA detects degradation products of C-terminal telopeptides of type II collagen. It is intended for in vitro diagnostic use as an indication of degradation of cartilage and may be used as an aid for the quantitative assessment of disease activity (structural damage of articular cartilage) in patients with rheumatoid arthritis (RA) and osteoarthritis (OA), the prognosis of disease activity in patients with RA and OA, and for the early assessment of long-term effect of therapy in patients with RA.

Disruption of the structural integrity of cartilage is the major histological finding in rheumatoid arthritis and osteoarthritis. Type II collagen is the major organic constituent of cartilage and fragments of type II collagen (CTX-II) are released into circulation and subsequently secreted into urine following degradation of cartilage. In urine, the CTX-II fragments can be quantified by Urine CartiLaps® (CTX-II) EIA.

The Urine CartiLaps® (CTX-II) EIA has been reported to be useful in the prediction of osteoarthritis progression¹-6 and in other clinical and pre-clinical investigations¹-17.

Urine CartiLaps® (CTX-II) EIA is based on the competitive binding of a monoclonal antibody to urinary fragments of type II collagen or to biotinylated, synthetic peptides bound to the surface of microtitre plates coated with streptavidin.

### Features and benefits

- Measures cartilage degradation in OA and RA
- Urine CTX-II is the most validated marker in these disease states
- Allows for dynamic monitoring of disease progression

# **Specifications**

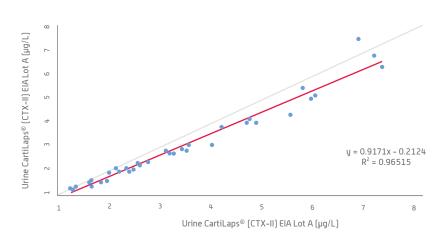
Format	Manual competitive monoclona	Manual competitive monoclonal antibody enzyme immunoassay				
Standards	Ready to use – 1 each of 6 conc	Ready to use $-1$ each of 6 concentration levels, $1 \times 3.0$ mL calibrator 0 and $1 \times 0.4$ mL of calibrators $1-5$				
Controls	Ready to use – 2 x 0.4 mL	Ready to use – 2 x 0.4 mL				
Minimum detectable	0.20 μg/L		• • • • • • • • • • • • • • • • • • • •			
Reference range	Population	n	Mean CTX-II (ng/mmol)	95% Confidence Interval (ng/mmol)		
	Males	247	278	87–895		
	All women	459	299	79–1137		
	Postmenopausal	256	363	112–1172		
Sample Volume	40µl		• • • • • • • • • • • • • • • • • • • •			
Sample Type	Urine – second morning void uri	Urine - second morning void urine specimens is recommended				
Reagent stability		Store the Urine CartiLaps® (CTX-II) EIA kit upon receipt at 2–8°C Under these conditions the kit is stable up to the expiry date stated on the box				
Precision	Sample ID	Mean (µg/L)	Inter Assay CV	Intra Assay CV		
	1	0.52	7.8%	12.2%		
	2	1.84	4.6%	10.8%		
	3	5.50	5.2%	6.9%		

## Lot to Lot Comparison

Urine CartiLaps® (CTX-II) EIA

46 samples (0.25 - 7.14 ng/mL) were assessed in 2 different lots of the Urine CartiLaps® (CTX-II) EIA

### Lot to lot comparison (n = 46)



# Ordering information

Product Name	Size	Code
Urine CartiLaps® (CTX-II) EIA	96 Wells	AC-10F1

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## **Complementary Products**

Product Name	Size	Code
Serum Pre-Clinical CartiLaps® (CTX-II) ELISA	96 Wells	AC-08F1
Urine Pre-Clinical CartiLaps® (CTX-II) EIA	96 Wells	AC-09F1
Human COMP® ELISA	96 Wells	AN-14-1006-71

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