

## Anti-CCP

ELISA for the determination of IgG antibodies against cyclic citrullinated peptides (CCP) in human serum



CE

### Product Highlights

- Use of synthetic cyclic citrullinated peptides (CCP)
- Excellent diagnostic efficiency, high sensitivity and specificity
- Automatable

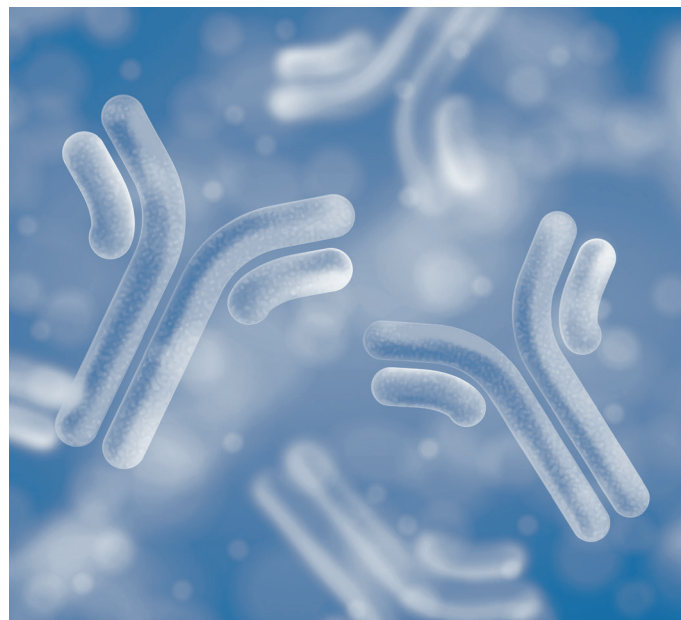
## **Antibodies against Cyclic Citrullinated Peptides** and their Importance in the Diagnosis of Rheumatoid Arthritis

**Rheumatoid arthritis** is the most common inflammatory joint disease. About 0.5 to 1.0 % of the population is affected worldwide. Painful joints in the fingers or toes are characteristic of rheumatoid arthritis, but knees, shoulders, hips or other joints may be also affected. The pain is often most pronounced in the morning. As the disease progresses, the number of affected joints usually increases.

The diagnosis of rheumatoid arthritis is based on the clinical symptoms, imaging methods and laboratory analysis. In routine diagnostic services, the serological determination of rheumatoid factors is one of the classic and most frequently performed analyzes initially. **Rheumatoid factors** are mostly IgM antibodies directed against IgG antibodies and are detectable in the majority of patients with rheumatoid arthritis. They are therefore considered to be a sensitive marker for laboratory confirmation of rheumatoid arthritis. However, rheumatoid factors also occur in other autoimmune diseases. Their evidence is therefore not considered proof of the disease. In addition, patients with rheumatoid arthritis without detectable rheumatoid factors have also been described.

Recently, the detection of antibodies against cyclic citrullinated proteins (CCP) has become increasingly important for the diagnosis of rheumatoid arthritis. The starting point was the observation that antibodies against filaggrin were frequently observed in patients with rheumatoid arthritis. More detailed investigations into the characterization of the epitopes established that these antibodies are directed in particular against

the citrullinated forms of filaggrin. The citrullination of proteins occurs enzymatically by deimination of arginine to citrulline. This modification is associated with a change in the charge state of the protein and thus in its structure and antigenic properties.



Instead of the isolated filaggrin, **cyclic citrullinated peptides** (CCP) with relevant epitopes are increasingly being used as the basis for immunoassays for the determination of specific **IgG antibodies**. Through the cyclization of synthetic peptides, the citrulline epitopes are placed in an exposed position, resulting in a significant improvement in the diagnostic properties – especially the specificity – of the test systems. Today, the determination of IgG antibodies against CCP serves as a **specific and early marker** for rheumatoid arthritis. In addition, the presence of CCP antibodies has a **high prognostic value** for an erosive course of the disease.

# Anti-CCP – Enzyme Immunoassay for the Determination of IgG Antibodies against Cyclic Citrullinated Peptides (CCP) in Human Serum



## Antigen

The Anti-CCP immunoassay for the detection of IgG antibodies is based on the use of synthetic cyclic citrullinated peptides with exposed epitopes.

## Calibration

The Anti-CCP immunoassay is calibrated using the anti-CCP reference reagent IS 2723 from the Centers of Disease Control and Prevention (CDC). Quantitative results are expressed in U/mL.

## Analytical Sensitivity

The analytical sensitivity was determined as limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ).

	ANALYTICAL SENSITIVITY
Limit of Blank (LoB)	0.2 U/mL
Limit of Detection (LoD)	0.4 U/mL
Limit of Quantitation (LoQ)	2.8 U/mL

## Analytical Specificity

The analytical specificity was assessed by addition of potentially interfering substances to samples. A significant influence of bilirubin (up to 342  $\mu\text{mol/L}$ ), hemoglobin (up to 2 g/L), triglycerides (up to 37 mmol/L) and biotin (up to 3500 ng/mL) on test results was not observed.

## Precision

The precision of test results was assessed by the determination of the intra- and interassay variation by the analysis of multiple samples with different antibody activities.

	INTRAASSAY PRECISION		INTERASSAY PRECISION	
	U/mL	CV (%)	U/mL	CV (%)
Sample 1	9.8	4.6	9.9	13.8
Sample 2	48.6	3.4	44.2	8.1
Sample 3	83.2	5.3	73.2	8.9

## Diagnostic Sensitivity and Specificity

Sensitivity and specificity were assessed by the analysis of 147 samples from patients with rheumatoid arthritis and 116 samples from unselected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	93.2 %
Specificity	> 99 %

## Publications

- Pruijn *et al.* (2010) The use of citrullinated peptides and proteins for the diagnosis of rheumatoid arthritis. *Arthritis Res. Ther.* 12, 203.
- Kurowska *et al.* (2017) The role of anti-citrullinated protein antibodies (ACPA) in the pathogenesis of rheumatoid arthritis. *Cent. Eur. J. Immunol.* 42, 390 – 8.
- Kroot *et al.* (2000) The prognostic value of anti-cyclic citrullinated peptide antibody in patients with recent-onset rheumatoid arthritis. *Arthritis Rheum.* 43, 1831 – 5.





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### HIGH QUALITY – MADE IN GERMANY

- Use of synthetic, cyclic, citrullinated peptides
- Ready-to-use (exception: wash buffer), color and barcoded reagents
- Quality assured handling in routine laboratories
- Short incubation times (60 min / 30 min / 15 min) at room temperature
- Quantitative determination of IgG antibody activity
- Calibrated using the international reference preparation IS 2723 of the Centers for Disease Control and Prevention (CDC)
- Excellent diagnostic sensitivity and specificity
- High precision within the measurement range
- CE certified
- Automatable

### Product Information

#### Anti-CCP



### Contact

GA Generic Assays GmbH

Ludwig-Erhard-Ring 3  
15827 Blankenfelde-Mahlow OT Dahlewitz  
Germany

Phone +49 (0) 33708 9286 0

Fax +49 (0) 33708 4417 25

[info@genericassays.com](mailto:info@genericassays.com)

[www.genericassays.com](http://www.genericassays.com)

### Order Information

#### Anti-CCP

(96 Determinations)

**REF 3665**