


EliA™ Autoimmune assays
Excellence in Autoimmunity

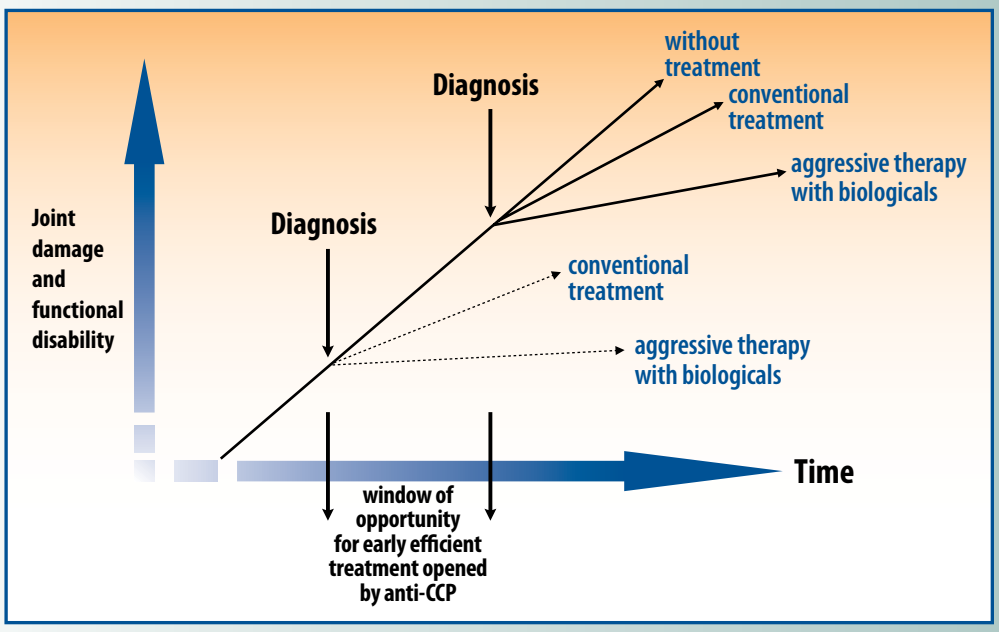
CCP antibodies (cyclic citrullinated peptide)

An early, specific marker for rheumatoid arthritis (RA)

Clinical rationale

- Early detection and intervention are essential for joint preservation and improved quality of life[1]
- CCP antibodies appear up to 10 years before the clinical diagnosis of RA[2]
- CCP antibodies demonstrate greater specificity than RF while maintaining or increasing sensitivity[3,4]
- CCP antibody results help physicians decide when aggressive therapy with biologicals is needed

Value of early diagnosis with CCP antibody testing[5]



Adapted from Klinkhoff.

"Irreversible joint erosion may occur early in the disease course in patients with rheumatoid arthritis (RA)…. Therefore, it is important to diagnose RA correctly and fast."[1]

— Vander Cruyssen B, et al

EliA™: Results make the difference

CCP antibodies

- The first fully automated, licensed, and patented anti-CCP clinical marker in the US
- Unparalleled technical performance
  - —Low variances and high reproducibility for consistent results
  - —High lot-to-lot consistency using validated production procedures
- Excellent specificity and sensitivity

"…not all commercially available methods for the detection of [CCP antibodies] have the same degree of diagnostic accuracy, and… careful selection is needed to obtain reliable results."[6]

— Bizzaro N, et al

Performance characteristics for early diagnosis[6]

Assay	Sensitivity at 98% specificity
EliA CCP antibodies	74%
Assay 1	64%
Assay 2	67%
Assay 3	67%
Rheumatoid factor (RF)	17%

Results from a comparative evaluation of second- and third-generation ELISA methods for the detection of antibodies to citrullinated proteins. Sensitivity and specificity of select kits are shown, along with those of RF, at cut-off levels provided by the manufacturers. Adapted from Bizzaro N, et al.

EliA: Automation makes it easy and economical

- Using the proven ImmunoCAP® 100ᵉ and ImmunoCAP 250 *automated* laboratory systems
- Moderately complex
- High efficiency for reduced labor costs and hands-on time
  - —Discrete single-well testing
  - —One calibration curve per isotype stored for 28 days
    - – IgA, IgE, IgG, IgM
- Onboard dilutions

References

1. Vander Cruyssen B, Nogueira L, Van Praet J, et al. Do all anti-citrullinated protein/peptide antibody tests measure the same? Evaluation of discrepancy between anti-citrullinated protein/peptide antibody tests in patients with and without rheumatoid arthritis. *Ann Rheum Dis*. 2008;67:542-546. **2.** Nielen MM, van Schaardenburg D, Reesink HW, et al. Specific autoantibodies precede the symptoms of rheumatoid arthritis: a study of serial measurements in blood donors. *Arthritis Rheum*. 2004;50(2):380-386. **3.** Bas S, Perneger TV, Seitz M, Tiercy JM, Roux-Lombard P, Guerne PA. Diagnostic tests for rheumatoid arthritis: comparison of anti-cyclic citrullinated peptide antibodies, anti-keratin antibodies and IgM rheumatoid factors. *Rheumatology (Oxford)*. 2002;41(7):809-814. **4.** Gilburd B, Praprotnik S, Showman O, Shoenfeld Y. Clinical diagnostic value of EliA™ fluorenzyme-immunoassay for anti-cyclic citrullinated peptide (CCP) antibodies in patients with rheumatoid arthritis. Paper presented at: 4th International Congress on Autoimmunity; November 2004; Budapest, Hungary. **5.** Klinkhoff A. Biological agents for rheumatoid arthritis: targeting both physical function and structural damage. *Drugs*. 2004;64(12):1267-1283. **6.** Bizzaro N, Tonutti E, Tozzoli R, Villalta D. Analytical and diagnostic characteristics of 11 2nd- and 3rd-generation immunoenzymatic methods for the detection of antibodies to citrullinated proteins. *Clin Chem*. 2007;53:1527-1533.

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