

White Paper

# A multicenter evaluation of a new automated method for measurement of anti-cyclic citrullinated peptide (aCCP)

# A multicenter evaluation of a new automated method for measurement of anti-cyclic citrullinated peptide (aCCP)

by M. Noordegraaf, A. Wolthuis, M. de Groot, F. Peters and R. Hoedemakers

Jeroen Bosch Hospital, 's-Hertogenbosch; Medical Center Leeuwarden, Leeuwarden; Bernhoven Hospital, Oss; Amphia Hospital, Breda; the Netherlands

## Background

Rheumatoid arthritis (RA) is a chronic inflammatory auto-immune disease and is mostly diagnosed based on clinical manifestations, but serological tests against autoantibodies are available. The presence of aCCP antibodies is strongly associated with a more severe, destructive disease course. Recently, a new test for the measurement of aCCP antibodies on the IMMULITE® 2000 XPi platforms was developed by Siemens Healthcare. In this study we investigated the performance of this new anti-CCP test in four different hospital laboratories.

## Methods

Samples were collected from patients presented to the hospital for aCCP measurement. Serum aCCP levels were determined by aCCP IgG assay for IMMULITE 2000 XPi systems (Siemens Healthcare), ImmunoScan RA Elisa test (Eurodiagnostica), Immunocap 250 (Phadia) or aCCP IgG assay on the Modular system (Roche Diagnostics).

**Table 1.** Within run and between run imprecision of aCCP immunoassay for IMMULITE 2000 XPi

	Within run		Between run	
	Level (U/mL)	VC (%)	Level (U/mL)	VC (%)
<b>Jeroen Bosch Hospital</b>	8.0	6.9	0	0
			8.4	5.6
			40.8	5.5
<b>Hospital Bernhoven</b>	5.3	4.5	0	0
	26.4	3.0	41.0	5.6
	171.2	3.8		
<b>Medical Center Leeuwarden</b>	3.2	8.8	3.2	11.0
	106.9	7.5	106.9	9.1

## Conclusion

The aCCP assay on the IMMULITE 2000 XPi has good performance characteristics and shows good concordance with the Immunoscan RA ELISA test, Immunocap 250 and aCCP test on the Roche Modular systems.

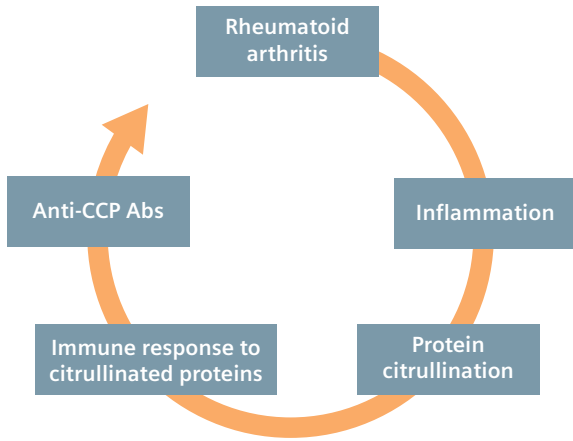


Figure 1. Possible role for aCCP in rheumatoid arthritis

		IMMULITE	
		NEG	POS
EURODIAGNOSTICA Concordance 90.2%	NEG	24	4
	POS	7	77
PHADIA Concordance 93.3%	NEG	70	1
	POS	6	28
ROCHE Concordance 94.8%	NEG	246	2
	POS	13	28

Figure 2: Concordance analysis for aCCP test on IMMULITE compared to Eurodiagnostica, Phadia and Roche

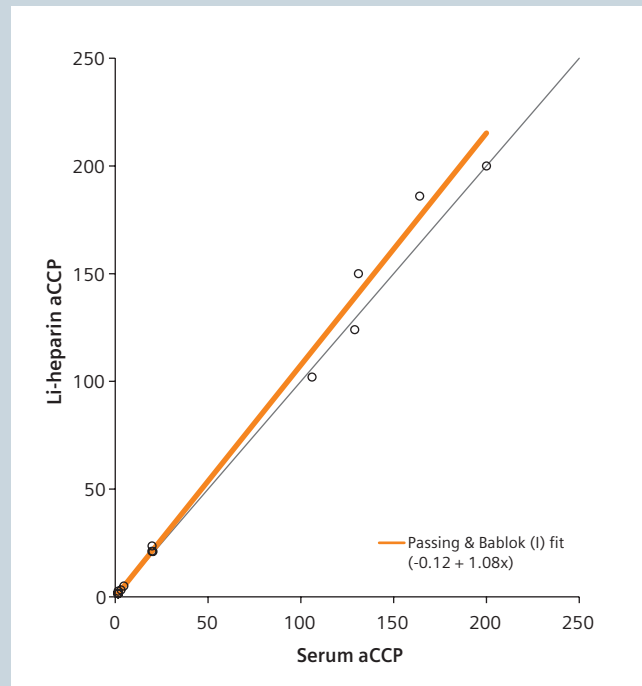
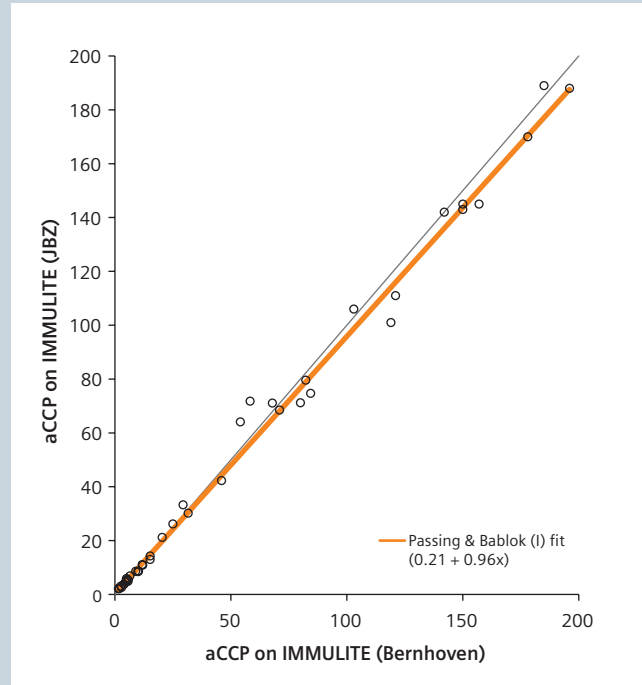


Figure 3: Passing and Bablok regression analysis for comparison between two different IMMULITE analyzers and serum-lithium comparison

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**Global Siemens Headquarters**

Siemens AG  
Wittelsbacherplatz 2  
80333 Muenchen  
Germany

**Global Siemens Healthcare  
Headquarters**

Siemens AG  
Healthcare Sector  
Henkestrasse 127  
91052 Erlangen  
Telephone: +49 9131 84-0  
Germany  
[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

**Global Division**

Siemens Healthcare Diagnostics Inc.  
511 Benedict Avenue  
Tarrytown, NY 10591-5005  
USA  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)