

• Specification

	ichroma™ Anti-CCP Plus	AFIAS Anti-CCP Plus
Sample type	Serum/Plasma/ Whole & Capillary blood	Serum/Plasma/ Whole & Capillary blood
Anti-coagulant	K ₂ EDTA, Na ₂ EDTA, Sodium Citrate	K ₂ EDTA, Na ₂ EDTA, Sodium Citrate
Sample volume	5 µL	30 µL (serum/plasma/whole blood) 10 µL (capillary blood using C-tip)
Assay time	12 min	12 min
Measurement range	3.5-300 U/mL	3.2-300 U/mL
Cut-off	5 U/mL	5 U/mL
CV	< 10%	< 10%
Storage	4-30 °C for cartridge 2-8 °C for detection buffer	2-8 °C
Shelf life	20 months	20 months

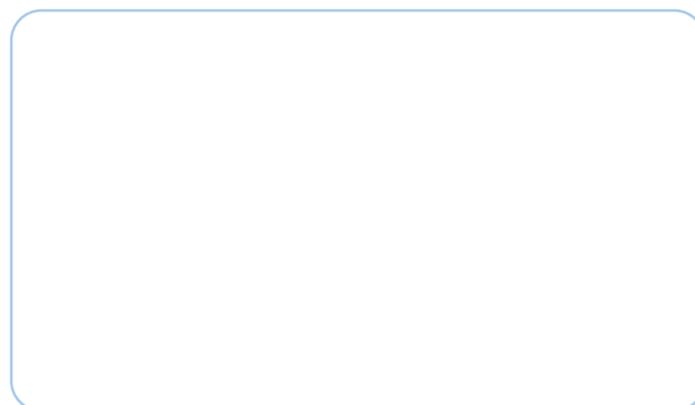
• Ordering information

Product	Cat. No.	Analyzer	Cat. No.
ichroma™ Anti-CCP Plus	CFPC-97	ichroma™ II	FPRR021
AFIAS Anti-CCP Plus	SMFP-67	AFIAS-6	FPRR020
Boditech Anti-CCP Plus Control	CFPO-288	AFIAS-1	FPRR019
		i-chamber	FPRR009



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EN_R0600_Anti-CCP Plus_20191105_Ap



ichroma™ Anti-CCP Plus AFIAS Anti-CCP Plus

Fast, On-site Blood Test for Diagnosing Rheumatoid Arthritis

- **Fast assay time**
Reliable result in 12 minutes
- **On-site test**
Simple test procedure
No sample preparation
Whole and capillary blood can be used
- **High accuracy**
Comparable result to automated analyzer
- **Cost-effectiveness**
No additional consumable
No daily QC



Find out more on www.boditech.co.kr



• What is the anti-CCP test?

The anti-cyclic citrullinated (anti-CCP) test can detect IgG autoantibodies against cyclic citrullinated peptides usually present in the blood of rheumatoid arthritis (RA) patients. The test has a moderate sensitivity (60-80%) and high specificity (> 95%) for RA¹.

• ACR/EULAR 2010 criteria for the diagnosis of RA

In 2010, the Rheumatoid Arthritis Classification Criteria were published by the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR). For the first time, the serologic criteria included measurement of anti-CCP as well as some definition of a low positive and high positive serology result².

Duration of symptom (0-1)	Points
< 6 weeks	0
≥ 6 weeks	1
Joint involvement (0-5)	
1 large joint	0
2-10 large joints	1
1-3 small joints (with or without involvement of large joints)	2
4-10 small joints (with or without involvement of large joints)	3
> 10 joints (at least 1 small joint)	5
Serology (0-3)	
Negative RF and negative anti-CCP	0
Low-positive RF or low-positive anti-CCP [#]	2
High-positive RF or high-positive anti-CCP [†]	3
Acute phase reactants (0-1)	
Normal CRP and normal ESR	0
Abnormal CRP or abnormal ESR	1

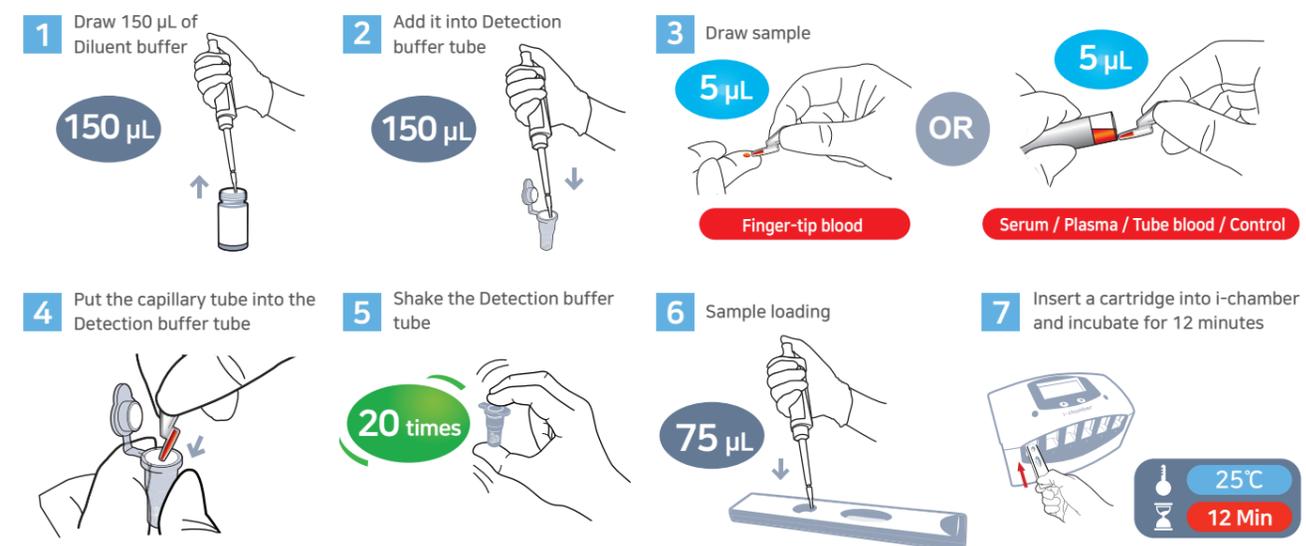
Defined RA = score 6 or more

[#] Low positive = ≤ 3 times cut-off

[†] High Positive = > 3 times cut-off

- 1. van Boekel MA et al. Arthritis Res 2002;4:87-93
- 2. Aletaha D et al. Arthritis Rheum 2010;62:2569-2581

• Test procedure (for ichroma™ Anti-CCP Plus)



• Performance

Total (n=150)	Axis-Shield (ELISA*) (> 5 U/mL)		Cobas e411 (ECLIA#) (> 17 U/mL)		
	Pos (n=75)	Neg (n=75)	Pos (n=70)	Neg (n=80)	
ichroma™ Anti-CCP Plus (> 5 U/mL)	Pos	72	0	69	3
	Neg	3	75	1	77
Positive agreement	96%		99%		
Negative agreement			100%		

Total (n=100)	Axis-Shield (ELISA*) (> 5 U/mL)		
	Pos (n=75)	Neg (n=75)	
AFIAS Anti-CCP Plus (> 5 U/mL)	Pos	55	1
	Neg	4	40
Positive agreement	93.2%		
Negative agreement	97.6%		

* Enzyme-linked immunosorbent assay

Electrochemiluminescence immunoassay

