BioCLIA® Autoimmune Control Set

CCP

CCP Assay Controls

Key to Symbols Used

REF	Catalog Number		Expiration Date
IVD	For *In Vitro* Diagnostic Use	LOT	Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in European Union
		Σ	Contains Sufficient for < *n* > Tests
Control L	Control 1		
Control H	Control 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Autoimmune Control Set, CCP

Intended Use

The BioCLIA Autoimmune Control Set, CCP is intended for the quality control purposes of the BioCLIA CCP performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00336 (2 X 1 mL)
MY00387 (4 X 1 mL)

Summary and Principles of the Procedure

Rheumatoid Arthritis (RA) is a chronic systemic disease mainly with inflammatory synovitis. About 1% of the world's people suffer from this disease in which 75% are women. [1] At present, in patients with suspected of RA, the most commonly used detection includes conventional inflammatory parameters, or rheumatoid factors (RFs) detection with 60-80% sensitivity in RA. However, RFs are also detected in healthy people, Systemic Lupus Erythematosus (SLE) or Sjogren's Syndrome patients, so RF is a sensitive but not very specific indicators for RA diagnosis. [2]

Antibodies to citrullinated protein antigens (ACPAs) are autoantibodies that are directed against peptides and proteins that are citrullinated. They are present in the majority of patients with RA. Clinically, cyclic citrullinated peptides (CCP) are frequently used to detect these antibodies with high sensitivity in patient serum or plasma. [3, 4, 5] Anti-CCP antibody is very useful in the early diagnosis of RA in high-risk groups, such as relatives of RA patients. [6] It is mainly in IgG types and having the same sensitivity but higher specificity at 95% for RA diagnosis. [7]

Materials supplied

- **CCP Control 1** A tube contains 1mL, ready to use reagent. Control 1 contains human antibodies to CCP in stabilizers and preservatives (Low). CCP | Control | L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **CCP Control 2** A tube contains 1mL, ready to use reagent. Control 2 contains human antibodies to CCP in stabilizers and preservatives (High). CCP | Control | H

Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value and acceptable range for the controls are indicated on control information sheet in each kit.

Warnings and Precautions

The human derived material in this product was tested by FDA approved methods and found nonreactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV 1/2 antibodies. Handle as if potentially infectious. [8] Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:

 Human serum is added in the controls.

 Proclin 300 is added in the controls at concentration between 0.0015% - 0.6%.

- The product is for *in vitro* diagnostic use only.
- Do not use any controls beyond their expiration dates. Do not mix controls from different lots unless specified.
- Instructions must be carefully followed for using and storing of controls. Any modification in procedure may interfere with the results. Controls and contaminated vials must be handled strictly following safety guidelines or rules of biological hazards to ensure the users' and environmental safety.
- Controls contain chemical and biological components. Avoid ingesting or splashing onto skin and mucous membrane. If direct contact with controls happens, rinse the contact surface with plenty of water immediately and see a doctor if necessary.

Storage Conditions

The kit is stable until the expiration date, if it is stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a control tube is opened, it is good for a total of 15 times, no more than 2 hours per time when kept uncapped, onboard the instrument, after which the reagent must be discarded. Three freeze-thaw cycles before testing has no effect on the kit reagents.

Assay Procedure

Note that, for obtaining optimal performance, it is important to perform all routine maintenance procedures as defined in the BioCLIA® 1200 and BioCLIA® 6500 User Manual.

See the BioCLIA® 1200 and BioCLIA® 6500 User Manual for preparation, setup, dilutions, adjustment, assay and quality control procedures.

The control procedure can be done before running the specimens each day. Users also can adjust the control procedure period according to their own lab frequency.

Limitations

This product is designed as controls for monitoring the performance of the BioCLIA CCP. These controls are subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

References

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management. The American journal of medicine 2007;120:936-39.
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3. Aletaha D, Neogi T, Silman AJ, Funovits J, Felson DT, Bingham CO, et al. 2010 rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis & Rheumatism 2010;62:2569-81.
4. Avouac J, Gossec L, Dougados M. Diagnostic and predictive value of anti-cyclic citrullinated protein antibodies in rheumatoid arthritis: a systematic literature review. Annals of the rheumatic diseases 2006;65:845-51.
5. Nishimura K, Sugiyama D, Kogata Y, Tsuji G, Nakazawa T, Kawano S, et al. Meta-analysis: diagnostic accuracy of anti–cyclic citrullinated peptide antibody and rheumatoid factor for rheumatoid arthritis. Annals of internal medicine 2007;146:797-808.
6. Goeldner I, Skare TL, de Messias Reason IT, Nisihara RM, Silva MB, da Rosa Utiyama SR. Anti-cyclic citrullinated peptide antibodies and rheumatoid factor in rheumatoid arthritis patients and relatives from Brazil. Rheumatology 2010:keq134.
7. Greiner A, Plischke H, Kellner H, Gruber R. Association of anti‐cyclic citrullinated peptide antibodies, anti‐citrullin antibodies, and IgM and IgA rheumatoid factors with serological parameters of disease activity in rheumatoid arthritis. Annals of the New York Academy of Sciences 2005;1050:295-303.
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Technical Assistance

For technical assistance, contact your National Distributor.

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