BioCLIA® Autoimmune Control Set

Cardiolipin Screen

Cardiolipin Screen 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, Cardiolipin Screen

Intended Use

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

Catalog Numbers

MY00327 (2 X 1 mL)
MY00378 (4 X 1 mL)

Summary and Principles of the Procedure

Antibodies against cardiolipin belong to the group of anti-phospholipid antibodies specific for negatively charged phospholipids, components of biological membranes. [1, 2]. Anti-phospholipid antibodies are frequently found in sera of patients with systemic lupus erythematosus (SLE) and related diseases. These specific anti-cardiolipin antibodies recognize epitopes on a complex composed of cardiolipin and β2-glycoproptein I which are only expressed when β2-glycoprotein I interacts with cardiolipin. [3, 4] The prevalence of anti-cardiolipin antibodies (aCL) in SLE is 50% and 5-40% in patients with systemic autoimmune disease like rheumatoid arthritis (RA), scleroderma, sjogren's syndrome or sharp syndrome. [5, 6]

The occurrence of anti-cardiolipin antibodies in patients with SLE and related diseases is typical of a secondary anti-phospholipid syndrome (APS). In contrast, anti-cardiolipin antibodies in patients with no other autoimmune diseases characterize the primary anti-phospholipid syndrome (APS). Many studies have shown a correlation between these autoantibodies and an enhanced incidence of thrombosis, thrombocytopenia and recurrent fetal loss. 80% of aCL positive patients develop venous or arterial thrombosis. Heart or brain infarction patients are often detected certain concentrations of aCL, indicating an increased risk of other vascular complications where patients' conditions and prognosis have to be monitored. On spontaneous stillbirth, miscarriage or premature birth, aCL can be found positive even for women without any autoimmune disease symptoms. [5, 6, 7]

Many immunoglobulin isotypes against aCL can be found including aCL-IgA, aCL-IgG and aCL-IgM. Level of aCL-IgG is highly correlated with thrombocytopenia, thrombosis or abortion; aCL-IgM is relevant to haemolytic anaemia; while aCL-IgA seems less linked to autoimmune diseases. [7]

Materials supplied

- **Cardiolipin Screen Control 1** A tube contains 1mL, ready to use reagent. Control 1 contains anti-aCL IgA/IgG/IgM antibodies in stabilizers and preservatives (Low).

aCL-A/G/M	Control	L

Preservatives: 0.0015% < Proclin 300 < 0.6%.

- **Cardiolipin Screen Control 2** A tube contains 1mL, ready to use reagent. Control 2 contains anti-aCL IgA/IgG/IgM antibodies in stabilizers and preservatives (High).

aCL-A/G/M	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 Cardiolipin Screen. 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

1. SCHLAME M, BRODY S, HOSTETLER KY. Mitochondrial cardiolipin in diverse eukaryotes. European Journal of Biochemistry 1993;212:727-33.
2. Houtkooper R, Vaz F. Cardiolipin, the heart of mitochondrial metabolism. Cellular and Molecular Life Sciences 2008;65:2493-506.
3. McNeil HP, Simpson RJ, Chesterman CN, Krilis SA. Anti-phospholipid antibodies are directed against a complex antigen that includes a lipid-binding inhibitor of coagulation: beta 2-glycoprotein I (apolipoprotein H). Proceedings of the National Academy of Sciences 1990;87:4120-24.
4. Schlame M, Horvath L, Vigh L. Relationship between lipid saturation and lipid-protein interaction in liver mitochondria modified by catalytic hydrogenation with reference to cardiolipin molecular species. Biochemical Journal 1990;265:79-85.
5. Spinella A, Lumetti F, Sandri G, Cestelli V, Mascia MT. Beyond cat scratch disease: a case report of bartonella infection mimicking vasculitic disorder. Case reports in infectious diseases 2012;2012.
6. Hokama Y, Campora CE, Hara C, Kuribayashi T, Le Huynh D, Yabusaki K. Anticardiolipin antibodies in the sera of patients with diagnosed chronic fatigue syndrome. Journal of clinical laboratory analysis 2009;23:210-12.
7. Pangborn MC. Isolation and purification of a serologically active phospholipid from beef heart. Journal of biological chemistry 1942;143:247-56.
8. Richmond JY, Mckinney RW. Biosafety in microbiological and biomedical laboratories: U.S.GPO. 1999.

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EC REP

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Technical Assistance

For technical assistance, contact your National Distributor.

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