









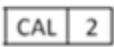




BioCLIA[®] Autoimmune Calibrator Set

Cardiolipin Screen

Cardiolipin Screen Assay Calibrators

Key to Symbols Used

	Catalog Number		Expiration Date
	For <i>In Vitro</i> Diagnostic Use		Lot Number
	Store between +2°C and +8°C		Consult Instruction for Use
	Manufacturer		Authorized Representative in European Union
	Calibrator 1		Contains Sufficient for $< n >$ Tests
	Calibrator 2		Chemical Risk Warning
			Biological Risk Warning

BioCLIA® Cardiolipin Screen Calibrator Set

Intended Use

The BioCLIA Autoimmune Calibrator Set, Cardiolipin Screen is intended for the calibration of the BioCLIA Cardiolipin Screen performed on the BioCLIA® 1200 and BioCLIA® 6500.

Catalog Numbers

MY00378 (2 X 1 mL)

MY00225 (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 β 2-glycoprotein I which are only expressed when β 2-glycoprotein I interacts with cardiolipin⁴. 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 diseases⁸.

Materials supplied

- **Cardiolipin Screen Calibrator 1** A tube contains 1mL, ready to use reagent. Calibrator 1

contains anti-aCL IgA/IgG/IgM antibodies in stabilizers and preservatives.

aCL-A/G/M	CAL	1
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

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

aCL-A/G/M	CAL	2
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Preservatives: 0.0015% < Proclin 300 < 0.6%.

Target value information is indicated in the 2D barcode localized 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.¹⁰ Avoid contacting with skin and eyes. Do not empty into drains. Wear suitable protective clothing.

Precautions:



Human serum is added in the calibrators.



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

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

Storage Conditions

The kit is stable until the expiration date, if stored and handled as directed. Routine store the kit in refrigerator (2-8°C). Once a calibrator 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.

Traceability

The reported values were determined over multiple runs on the BioCLIA® 1200 and BioCLIA® 6500 using specific lots of reagents against an in-house standard. Cardiolipin Screen results are reported in RU/mL which is interpreted from relative light unit (RLU). Method comparison test showed good sensitivity and specificity of tested assay.

Limitations

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

References

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Technical Assistance

For technical assistance, contact your National Distributor.

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Revision 9



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