BioVendor Group CLIA

Antiphospholipid syndrome

Beta 2 Glycoprotein
Cardiolipin

Diagnostic panel

IVD CE 2265

Diagnostic kits are intended for professional use in the laboratory.

Designed for the platform Kleeya®


diatron

Antiphospholipid syndrome

Antiphospholipid syndrome (APS) is an autoimmune disorder characterized by an increased occurrence of thrombosis, thromboembolism, miscarriage, and preeclampsia. It is classified as primary, which occurs as an independent condition without a known cause of antibody production, and secondary, which is associated with another autoimmune disease or malignancy, such as systemic lupus erythematosus, rheumatoid arthritis, or Sjögren's syndrome.

Phospholipids

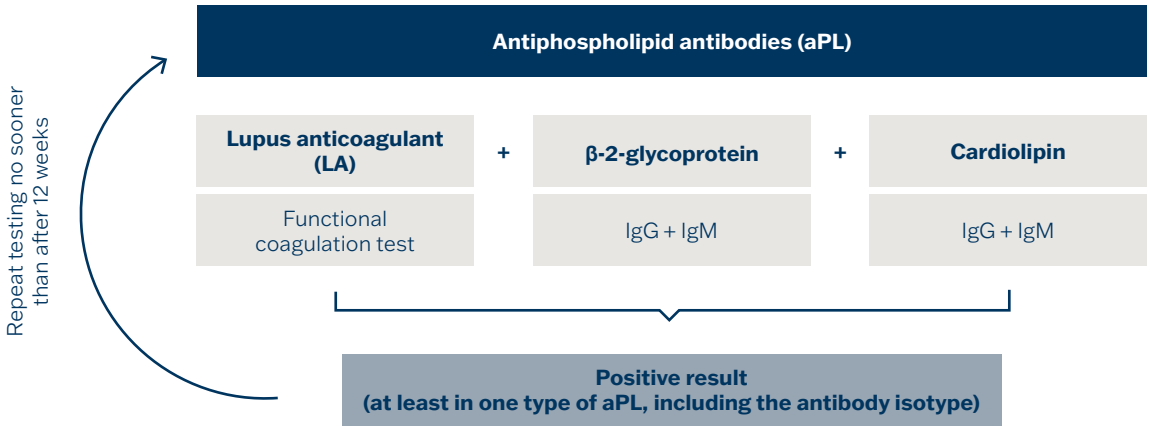
The phospholipid cardiolipin is a major structural component of the inner mitochondrial membrane and is also present in the plasma membrane of certain prokaryotes. Because antibodies against cardiolipin alone commonly occur in infectious diseases, diagnostic tests therefore utilize a complex epitope composed of cardiolipin and β2-glycoprotein. β2-glycoprotein, also known as apolipoprotein H (Apo-H), is dissolved in blood serum, where it assists in coagulation and binds to negatively charged phospholipids such as cardiolipin. Upon binding to cardiolipin, β2-glycoprotein undergoes a conformational change, enabling specific anticardiolipin antibodies to bind to this complex.

Diagnosis of disease

The diagnosis of APS is based on a combination of clinical manifestations (such as a history of thrombosis, spontaneous abortion, thrombocytopenia, or stroke) and laboratory findings (including the presence of IgM/IgG autoantibodies against cardiolipin and β2-glycoprotein, lupus anticoagulant antibodies, and coagulation tests). A positive autoantibody test must be successfully repeated after 12 weeks; otherwise, it is considered a transient or false positive result. Such findings may be caused by infectious agents (e.g., HIV, HBV, HCV, *Treponema pallidum*, *Mycobacterium tuberculosis*, *Mycobacterium leprae*, *Borrelia* species, *Toxoplasma gondii*) or certain medications (such as phenytoin, chlorpromazine, phenothiazines, procainamide, quinidine, and hydralazine).

In individuals suspected of having antiphospholipid syndrome, IgG and/or IgM autoantibodies against β2-glycoprotein alone or against the β2-glycoprotein–cardiolipin complex are diagnostically significant. IgA autoantibodies have only supportive diagnostic value.

Testing scheme



Supplementary testing

β-2-glycoprotein	Cardiolipin	Phosphatidylserine	Prothrombin
IgA	IgA	Antibodies	Antibodies
Antibodies against domain I			

According to Devreese, K. M. J., Bertolaccini, M. L., Branch, D. W., de Laat, B., Erkan, D., Favaloro, E. J., Pengo, V., Ortel, T. L., Wahl, D., & Cohen, H. (2024). An update on laboratory detection and interpretation of antiphospholipid antibodies for diagnosis of antiphospholipid syndrome: Guidance from the ISTH-SSC Subcommittee on Lupus Anticoagulant/Antiphospholipid Antibodies. Journal of Thrombosis and Haemostasis. Advance online publication. https://doi.org/10.1016/j.jtha.2024.10.022.

Clinical application

– Support in diagnosing antiphospholipid syndrome (APS) and other autoimmune diseases

Antigens

CLIA Beta 2 Glycoprotein

Highly purified native β-2-glycoprotein 1 antigen

CLIA Cardiolipin

A mixture of highly purified native β-2-glycoprotein 1 antigen and cardiolipin liposomes

Test characteristics

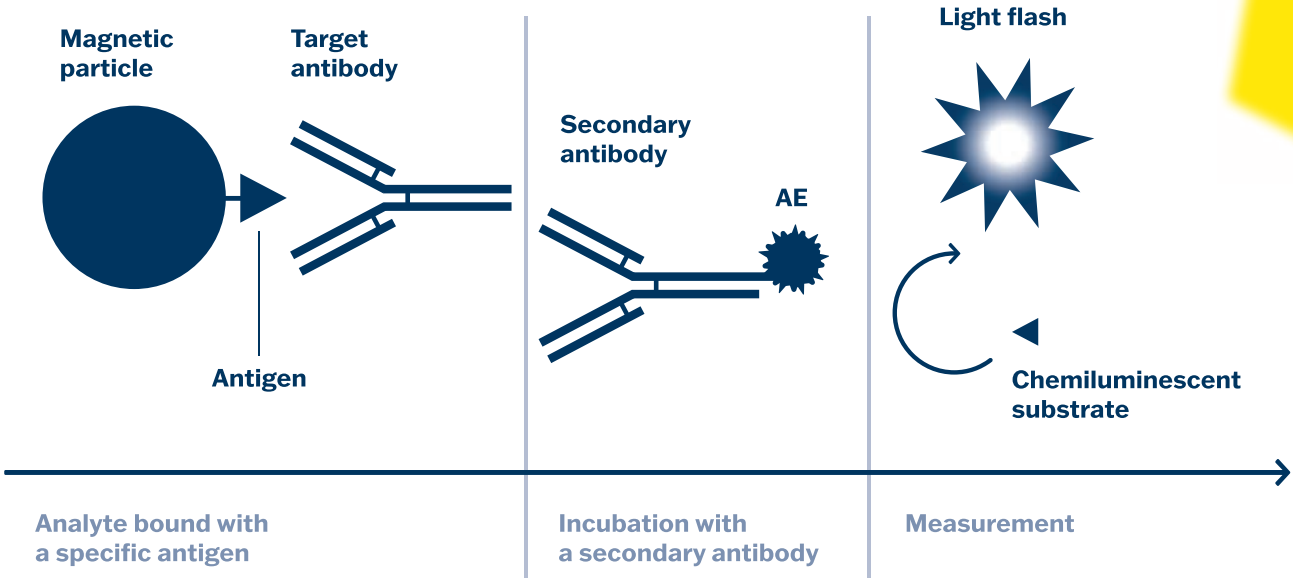
Kit	Calibration range	Diagnostic sensitivity	Diagnostic specificity	Evaluation
CLIA Beta 2 Glycoprotein IgA	0–300 U/ml	99.99%	92.00%	U/ml
CLIA Beta 2 Glycoprotein IgG	0–300 IU/ml	97.44%	94.05%	IU/ml*
CLIA Beta 2 Glycoprotein IgM	0–300 U/ml	97.06%	99.99%	U/ml
CLIA Cardiolipin IgA	0–300 APL/ml	88.57%	90.91%	APL/ml**
CLIA Cardiolipin IgG	0–300 GPL/ml	95.71%	84.72%	GPL/ml**
CLIA Cardiolipin IgM	0–300 MPL/ml	86.96%	85.71%	MPL/ml**

* Quantitative evaluation in international units was derived from the WHO international standard WHO (21/266) and reference material (ERM-DA477/IFCC).

** In the quantitative evaluation, reference calibrators from N.E. Harris, Louisville (Louisville APL Diagnostics) were considered, as well as the comparison with the results of reference methods using the same units derived from these reference calibrators.

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines magnetic particle-mediated antigen / antibody immunocomplex separation and flash chemiluminescence to achieve sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa®automated platform.



CLIA kits

Diagnostic CLIA kits are used as an aid in the diagnosis of APS and other autoimmune diseases by determining anticardiolipin antibodies and antibodies against beta-2 glycoprotein in human serum or plasma in the general population.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Qunatitative determination
- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Control sera available as independent sets

Advantages

- High diagnostic sensitivity and specificity
- Short test time (30-40 min)
- Low sample (10 µl) and reagent consumption
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service
- Alignment with reference materials and standards

Ordering information

CLIA kits

CLIA diagnostic kits are used to determine specific antibodies in human serum or plasma on a KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA Beta 2 Glycoprotein IgA	CL-BGA100	100
CLIA Beta 2 Glycoprotein IgG	CL-BGG100	100
CLIA Beta 2 Glycoprotein IgM	CL-BGM100	100
CLIA Cardiolipin IgA	CL-CLA100	100
CLIA Cardiolipin IgG	CL-CLG100	100
CLIA Cardiolipin IgM	CL-CLM100	100

Control sets

Each set contains two vials of positive and two vials of negative control serum with the predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Control set	Catalogue number	Number of tests
Control set CLIA Beta 2 Glycoprotein IgA	CL-BGACON	2 x 20
Control set CLIA Beta 2 Glycoprotein IgG	CL-BGGCON	2 x 20
Control set CLIA Beta 2 Glycoprotein IgM	CL-BGMCON	2 x 20
Control set CLIA Cardiolipin IgA	CL-CLACON	2 x 20
Control set CLIA Cardiolipin IgG	CL-CLGCON	2 x 20
Control set CLIA Cardiolipin IgM	CL-CLMCON	2 x 20

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DISTRIBUTOR

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