



Anti-Cardiolipin

Autoimmune EIA

Antiphospholipid Syndrome and Antiphospholipid Antibodies

Antiphospholipid Syndrome (APS) is a term used to describe the association between clinical syndrome of venous and arterial thrombosis, recurrent fetal loss, thrombocytopenia and the presence of persistent antiphospholipid antibodies.^{1,2} Other clinical conditions associated with the syndrome include stroke, heart attack, endocarditis and hemolytic anemia.³ The syndrome is termed “primary” if there is no accompanying autoimmune disease and “secondary” if the patient also has Systemic Lupus Erythematosus (SLE) or another autoimmune disorder.¹

Antiphospholipid antibodies (aPL) are a family of related but distinct autoantibodies of IgG, IgM and IgA classes that are directed against anionic phospholipids, phospholipid/protein complexes, and protein cofactors in the absence of phospholipid. aPL can be divided into the lupus anticoagulants (LA) detected by in vitro clotting tests, and antibodies detected by solid-phase enzyme-linked immunosorbent assays (ELISA), which include anti-Cardiolipin antibodies (aCL), anti- β 2 Glycoprotein I antibodies (β 2 GPI), anti-Phosphatidylserine antibodies (aPS), and anti-Prothrombin antibodies (aPT).^{2,3}

Anti-Cardiolipin Testing

The aCL assay serves to assist in the diagnosis of Antiphospholipid syndrome. This diagnosis has important implications for the treatment and prediction of recurrent thrombosis and recurrent miscarriage.²

The Bio-Rad anti-Cardiolipin Test Kits are enzyme-linked immunosorbent assays (ELISA) for the detection and semi-quantitative determination of aCL IgG, IgM or IgA antibodies in human serum or plasma. The results are reported in GPL, MPL, and APL units that are directly traceable to an internationally recognized reference preparation. The Bio-Rad anti-Cardiolipin Test Kits are intended to be used by clinical (hospital and reference) laboratories.

Product Highlights

- Specific determinations of IgG, IgM and IgA aCL antibodies
- Flexible multi-point or single-point calibration options
- Better regression analysis with distinct calibrators
- Built-in quality-control with undiluted controls and calibrators

Anti-Cardiolipin (aCL)

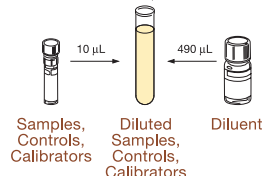
Autoimmune ELISA Procedure – Anti-Cardiolipin

Pre-Test Setup Instructions

- 1 Bring all reagents to room temperature (18–26°C).
- 2 Prepare the Wash Solution.

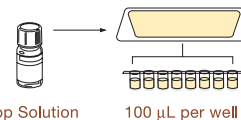
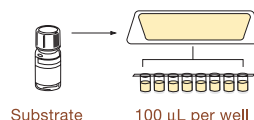
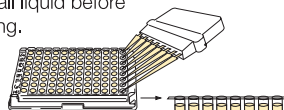
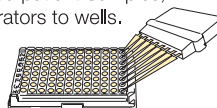


- 3 Make 1:50 working solutions by diluting 10 µL of patient's sera Positive/Negative Controls and 3 Calibrators in 490 µL of Diluent.



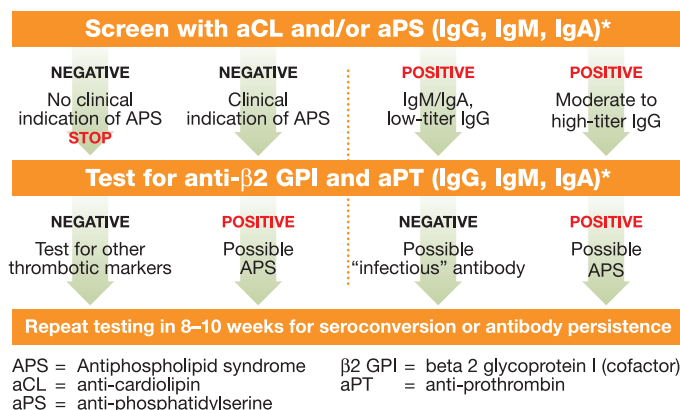
Test Procedure (See Procedure Notes and Pre-Test Setup Instructions)

- 1 Apply 100 µL diluted patient Samples, Controls and Calibrators to wells.
- 2 Incubate wells for 30–40 minutes at room temperature (18–26°C).
- 3 Wash wells 4x with 250 µL of Wash Solution. Remove all liquid before proceeding.
- 4 Apply 100 µL HRP Conjugate to all wells.
- 5 Incubate for 30–40 minutes at room temperature (18–26°C).
- 6 Wash wells 4x with 250 µL of Wash Solution. Remove all liquid before proceeding.
- 7 Develop color by adding 100 µL Substrate to each well. Discard excess transferred Substrate after use.
- 8 Incubate for 30–40 minutes at room temperature (18–26°C).
- 9 Stop color development by adding 100 µL of Stop Solution to each well.
- 10 Read results within 30 minutes with an EIA reader set to 450 nm.



aPL Testing Algorithm

Antiphospholipid Antibody Screening Procedure



* Screen for each isotype. Polyvalent screen not recommended.

Cut-Off Value

- aCL IgG: <23 GPL units
- aCL IgA: <22 APL units
- aCL IgM: <11 MPL units

Ordering Information

| Catalog No. | Description |
|-------------|---|
| 425-2000 | Anti-Cardiolipin IgG Test Kit.....96 tests |
| 425-2020 | Anti-Cardiolipin IgM Test Kit.....96 tests |
| 425-2040 | Anti-Cardiolipin IgA Test Kit96 tests |

REFERENCES

1. Asherson RA., Cervera R., Piette J., and Shoenfeld Y. Milestones in the Antiphospholipid Syndrome. *The Antiphospholipid Syndrome II: Autoimmune Thrombosis*.
2. Reddel SW., and Krilis SA. Testing for and Clinical Significance of Anticardiolipin Antibodies. *CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY*, Nov, 1999, p. 775-782
3. Hill HR et al., Anti-Phospholipid Testing. ARUP Lab home page.

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