DiaPharma Anti-Cardiolipin Assay

For In Vitro Diagnostic Use

- **Specific determination of IgG, IgM, or IgA aCL antibodies**
- **Convenient ELISA Procedure**
- **Objective, accurate and reproducible**
- **Reagent complete kit**
- **Short incubations at room temperature**

Anti-Cardiolipin Antibodies*

Anti-cardiolipin (aCL) antibodies are associated with the presence of both venous and arterial thrombosis, thrombocytopenia, and recurrent fetal loss. These autoantibodies are frequently found in patients with systemic lupus erythematosus (SLE) and other autoimmune diseases, as well as in some individuals with no apparent previous underlying disease. The term "anti-phospholipid syndrome" (APS) has been introduced to describe patients who present these clinical manifestations, in association with aCL antibodies or the lupus anticoagulant.

Principle*

The DiaPharma aCL test kits utilize a convenient ELISA procedure with single point calibration to detect specific isotypes of aCL antibodies in human serum or plasma. Solid-phase immunoassays are generally considered more sensitive and more specific for detecting aCL antibodies than coagulation assays. The Diapharma Anti-Cardiolipin Test Kit provides rapid, highly reproducible, accurate, objective results. Test kits are available for the semi-quantitative determination of IgG/IgM, and IgA immunoglobulins.

DiaPharma aCL Procedure

Diluted patient serum (preferred) or plasma is incubated in coated microwells. Cardiolipin antibodies present in the sample will bind to the coated wells. After washing to remove unbound plasma proteins, enzyme conjugated anti-human immunoglobulin specific for either IgG, IgM, or IgA is added. The wells are washed again, and a chromogenic substrate is added, resulting in a colored product. The reaction is stopped by the addition of a weak acid solution, and the colored product is measured in a spectro-photometer at 450 nm. Test results are available in less than one hour. Values for aCL antibodies are reported in GPL, MPL, and APL units, with assay cutoffs established at 23 GPL, 11 MPL, and 22 APL.

Clinical Performance*

Clinical Specificity: Assay cutoffs were challenged with a healthy blood donor population. Using the stated cutoffs, the assays were 97% specific for IgG, 96% specific for IgM, and 95% specific for IgA.

Clinical Sensitivity: The percentage of positives exhibited by 2 disease state populations is summarized in the tables below:

Group 1: SLE + Thrombosis and/or thrombocytopenia

	IgG aCL	IgM aCL	IgA aCL
Average value	34 GPL	11 MPL	30 APL
% positive	59%	43%	75%

Group 2: Primary APS

	IgG aCL	IgM aCL	IgA aCL
Average value	43 GPL	14 MPL	23 APL
% positive	64%	50%	46%

Ordering Information:

DiaPharma IgG/IgM Anti-cardiolipin
Catalog # 10297 96 well kit

DiaPharma IgA Anti-cardiolipin
Catalog # 10298 96 well kit

***Data available upon request.**

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