

**REAADS Anti-Cardiolipin
Test Kits**
For In Vitro Diagnostic Use

REAADS

Anti-Cardiolipin IgG/IgM Test Kit

Product #: 023-001

(96 well kit)

Product #: 023-002

(288 well kit)

REAADS

Anti-Cardiolipin IgA Test Kit

Product #: 026-001

(96 well kit)

Product #: 026-006

(288 well kit)

- **Convenient, cost effective ELISA Procedure**
- **For the specific determination of IgG, IgM, or IgA isotypes**
- **Reagent complete kits**
- **Total incubation time: 40 minutes at room temperature**
- **Excellent clinical correlation**
- **Choice of single or multi-point calibration**

Background

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.

Principle

The REAADS Anti-Cardiolipin ELISAs are semi-quantitative, indirect enzyme linked immunosorbent assays for the detection of IgG, IgM and IgA anti-cardiolipin antibodies in human serum or plasma. The assays use a single or multi-point calibrator to obtain aCL antibody concentrations in patient samples. Test kits for the specific semi-quantitative determination of IgG or IgM and IgA immunoglobulins are available. Assay results (in GPL, MPL or APL units) are traceable to an internationally recognized standard.

Procedure

Controls and patient samples are diluted with sample diluent containing bovine serum (source of cofactor) and incubated in cardiolipin coated microwells. Cardiolipin antibodies present in the sample will bind to the coated wells. After washing, enzyme conjugated anti-human immunoglobulin specific for IgG, IgM or IgA is added. Following a wash to remove any unbound sample, antibodies specific to human IgG, IgM or IgA labeled with horseradish peroxidase (HRP) are added to the wells. After washing to remove unbound conjugate, a chromogenic substrate is added, resulting in a soluble colored product that is measured in a spectrophotometer at 450nm following the addition of a stop solution. Relative patient aCL levels are determined by comparing the absorbance of patient wells to those of the calibrator. Total incubation is 40 minutes at room temperature. Results for aCL antibodies are reported in GPL, MPL, and APL units with assay cutoffs established at 23, 11 and 22 units respectively for IgG, IgM and IgA.

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Clinical Performance

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

Clinical Sensitivity: unselected SLE populations were tested to determine assay sensitivity; 21% of the samples were positive

for IgG, 10% for IgM and 26% for IgA antibodies with the REAADS aCL assays. The clinical sensitivity for thrombosis and thrombocytopenia was determined by comparing aCL test results from two groups of selected SLE patients: Group 1 – with a clinical history of thrombosis and/or thrombocytopenia; and Group 2 – with no history of thrombosis or thrombocytopenia (control). The results are shown in the charts below:

Group 1: SLE + Thrombosis and/or thrombocytopenia			
	IgG aCL	IgM aCL	IgA aCL
Average Value	30 GPL	9 MPL	32 APL
% positive	45%	25%	79%

Group 2: SLE control			
	IgG aCL	IgM aCL	IgA aCL
Average Value	8 GPL	3 MPL	15 APL
% positive	0%	0%	0%

L.Lopez, M. Santos, L. Espinoza, F. LaRosa.
Clinical Significance of IgA vs. IgG and IgM aCL Antibodies in patients with SLE. Am J Clin Path, 1992; vol. 98, No. 4; 449-454.



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