



## User's Manual

# Cardiolipin Screen ELISA Kit



DEIABL326



96T



This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

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### Creative Diagnostics

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## PRODUCT INFORMATION

### Intended Use

Cardiolipin Screen ELISA is a solid phase enzyme immunoassay employing highly purified cardiolipin plus native human  $\beta$ 2-glycoprotein I for the combined quantitative and qualitative detection of IgA, IgG and IgM antibodies against cardiolipin in human serum. Anti-cardiolipin antibodies mainly recognize specific epitopes on a complex composed out of cardiolipin and  $\beta$ 2-glycoprotein I which are expressed only when  $\beta$ 2-glycoprotein I interacts with cardiolipin.

The assay is an aid in the diagnosis and risk estimation of thrombosis in patients with systemic lupus erythematosus (SLE).

### General Description

Cardiolipin Screen ELISA is a solid phase enzyme immunoassay employing highly purified cardiolipin plus native human  $\beta$ 2-glycoprotein I for the combined quantitative detection of IgA, IgG and IgM antibodies against cardiolipin in human serum. Anti-cardiolipin antibodies mainly recognize specific epitopes on a complex composed out of cardiolipin and  $\beta$ 2-glycoprotein I which are expressed only when  $\beta$ 2-glycoprotein I interacts with cardiolipin. The assay is an aid in the diagnosis and risk estimation of thrombosis in patients with systemic lupus erythematosus (SLE). Antibodies against cardiolipin belong to the group of anti-phospholipid antibodies specific for negatively charged phospholipids, components of biological membranes. Cardiolipin is an acidic phospholipid derived from glycerol and was named because of its isolation from bovine heart in 1941. Anti-phospholipid antibodies are frequently found in sera of patients with systemic lupus erythematosus (SLE) and related diseases. The prevalence of anti-cardiolipin antibodies in SLE is 24-50 %. The occurrence of anti-cardiolipin antibodies in patients with SLE and related diseases is typical for 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 habitual abortions (as a consequence of placental infarct). The exact mechanism by which pathogenic anti-phospholipid antibodies induce thrombosis is not yet revealed fully.

### Storage

2-8°C

### Precision

Intra-assay		
Sample No.	Mean (U/ml)	CV (%)
1	586.2	1.5
2	67.4	3.4
3	34.5	7.6

Inter-assay		
Sample No.	Mean (U/ml)	CV (%)
1	499.8	0.9
2	68.9	1.7
3	40.7	4.6

### Detection Range



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0 - 300 U/mL, cut-off 20 U/mL

## **Sensitivity**

1.0 U/ml