



**User's Manual**

# Serin-Prothrombin IgG / IgM ELISA Kit



**DEIABL367**



**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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## PRODUCT INFORMATION

### Intended Use

Serin-Prothrombin IgG ELISA is a solid phase enzyme immunoassay with highly purified human phosphatidyl-serine plus native human prothrombin for the quantitative and qualitative detection of IgG and/ or IgM antibodies against phosphatidyl-serine and prothrombin in human serum.

The assay is an aid in the diagnosis and risk estimation of thrombosis in patients with systemic lupus erythematosus and anti-phospholipid syndrome (APS).

### General Description

Serin-Prothrombin IgG/IgM ELISA is a solid phase enzyme immunoassay with highly purified phosphatidyl-serine plus native human prothrombin for the combined quantitative detection of IgG and / or IgM antibodies against phosphatidyl-serine and prothrombin in human serum. The assay is an aid in the diagnosis and risk estimation of thrombosis in patients with systemic lupus erythematosus and anti-phospholipid syndrome (APS). Antibodies against prothrombin and phosphatidyl-serine, an acidic phospholipid derived from glycerol, belong to the group of anti-phospholipid antibodies specific for phospholipids such as cardiolipin, phosphatidyl- inositol, -ethanolamin, -choline, sphingomyelin, phosphatidic acid and prothrombin. Phospholipids are components of biological membranes. Prothrombin (human factor II) is a plasme zymogen with a molecular weight of 72 kDa. It assembles with the activated forms of Factor V, Factor X and phospholipid to form a catalytic unit known as the prothrombinase complex. In the presence of calcium ions, the complex cleaves the membrane-associated prothrombin into thrombin, which is then released into the soluble phase. Anti-phospholipid antibodies are frequently found in sera of patients with systemic lupus erythematosus (SLE) and related diseases. The occurrence of anti-phospholipid antibodies in patients with SLE and related diseases is typical for a secondary anti-phospholipid syndrome (APS). In contrast, antiphospholipid antibodies in patients with no other autoimmune diseases characterize the primary 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 infarction). The exact mechanisms by which pathogenic anti-phospholipid antibodies induce thrombosis is not yet revealed fully. Antibodies targeting prothrombin alone have recently been described being highly associated with fetal loss in APS patients. Prothrombin antibodies are the first marker for this serious complication as all other known antiphospholipid antibodies failed to correlate with fetal loss. Additionally, antibodies targeting a complex of prothrombin and phosphatidylserine have been associated with the second major group of clinical manifestations of the APS, venous and arterial thrombosis. However, they failed to show any correlation with fetal loss. Therefore, both types of antibodies serve as an important diagnostic tool for differential diagnosis of the heterogenous manifestations of the APS.

### Storage

2-8°C

### Precision

Intra-Assay		
Sample No.	Mean (U/ml)	CV (%)
1	133.0	3.8
2	74.0	4.2
3	42.0	4.3

Inter-Assay		
Sample No.	Mean (U/ml)	CV (%)
1	138.0	4.2
2	79.0	5.8
3	38.0	4.9

## Detection Range

0 - 300 U/mL, cut-off 15 U/mL

## Sensitivity

1.0 U/ml