



## DiaPharma Anti-Prothrombin Test Kit

- Convenient ELISA procedure
- For the specific determination of IgG and IgM isotypes
- Objective, accurate and reproducible
- Reagent complete kits
- Total incubation time: 40 minutes at room temperature

### BACKGROUND

Several plasma proteins associated with the coagulation system and with strong phospholipid binding properties have been identified as antiphospholipid cofactors. Antibodies to prothrombin, one of these plasma proteins, have been reported in patients with antiphospholipid syndrome. Testing for these antibodies is proposed to be included in the serologic evaluation of antiphospholipid antibodies. Clinically, elevated serum levels of anti-prothrombin (aPT) antibodies are associated with an increased risk for APS, characterized by recurrent arterial or venous thrombosis, thrombocytopenia and/or fetal loss. High serum or plasma levels of aPT antibodies may add valuable information in the laboratory assessment of antiphospholipid antibodies.

### PRINCIPLE

The DiaPharma IgG and IgM anti-Prothrombin antibody test kits are semiquantitative, indirect ELISAs for the detection of antibodies against human prothrombin. A single point calibrator is used to determine IgG or IgM anti-prothrombin antibody concentrations in human serum of citrated plasma.

### PROCEDURE

Diluted patient serum or plasma is incubated in microwells coated with human prothrombin. Anti-Prothrombin (aPT) antibodies in patient samples will bind to the immobilized antigen in the wells. After washing to remove unbound serum or plasma proteins, antibodies specific for human IgG or IgM, labeled with horseradish peroxidase (HRP), are bound antibodies. The wells are washed, and a chromogenic substrate is added, resulting in a color change that is proportional to the amount of antibody present. The assay is completed by the addition of a stopping solution. Results are obtained by reading the O.D. (optical density or absorbance) at 450nm of each well in a spectrophotometer. The O.D. values of control and patient samples are multiplied by the calibrator conversion factor to obtain IgG or IgM aPT antibody concentrations time is 40 minutes at room temperature.

### CLINICAL PERFORMANCE\*

**Clinical Specificity:** serum samples from 100 healthy blood donors were tested for aPT antibodies. Against an established cutoff value of 20 G and 20 M units, the specificity of the IgG assay was 95%, while the specificity of the IgM assay was 97%. As presented in the table below, similar results were seen when plasma samples from 100 healthy blood donors were tested. Assay specificity with 42 infectious disease (syphilis) patients and 42 Rheumatoid Arthritis (RA) patients is also presented in the table.

**Clinical Sensitivity:** serum samples from 41 unselected SLE patients were tested for IgG and IgM aPT antibodies. 14.6% of the samples were positive for IgG and 12.2% of the samples were positive for IgM aPT antibodies (mean values of 10.4 G units and 11.8 M units, respectively). Serum samples from 11 selected female patients with primary anti-phospholipid syndrome (APS) were also evaluated for antibodies to prothrombin. 18.2% of the samples were positive for IgG and 27.3% were positive for IgM antibodies (mean values of 12.3 G units and 15.7 M units).

	IgG aPT (% positive)	IgM aPT (% positive)
Healthy serum (n=100)	5%	3%
Healthy plasma (n=100)	1%	3%
Syphilis (n=42)	4.8%	11.9%
RA (n=42)	4.8%	4.8%
SLE (n=41)	14.6%	12.2%
APS (n=11)	18.2%	27.3%

### ORDERING INFORMATION

*For in-vitro diagnostic use*

**IgG Anti-Prothrombin Test Kit** 96 well kit  
**Catalog # K10238**

**IgM Anti-Prothrombin Test Kit** 96 well kit  
**Catalog # K10240**

\*Data available upon request.