Cambridge Biomedical

Anti-Phospholipid Antibodies in Serum (Acid, Choline, Ethanolamine, Glycerol, and Inositol)

1.0

Specimen Type	Serum
Specimen Volume	≥ 1 mL for each aPL IgG, IgM, and IgA panel.
Collection	Red top tube or SST tube. After collection, allow blood to clot for 30 minutes. Centrifuge at 3,000 rpm for 10 minutes. Separate serum and freeze immediately. Ship frozen.
Minimum Volume	0.5 mL
Handling	Ship frozen on dry ice.
Rejection Criteria	Hemolyzed specimens. Lipemic specimens Microbially contaminated specimens. Ambient temperature specimens. More than 1 freeze-thaw cycles. Specimens outside of listed stability.
Stability*	Frozen for 30 days. Refrigerated for 14 days.
Methodology	ELISA

Antiphosphotidic Acid
Anti-Phosphatidyl-Choline, Ethanolamine, Glycerol & Inositol

	IgG	IgM	IgA
Negative	< 12.0 U/mL	< 12.0 U/mL	< 12.0 U/mL

Turnaround Time	Up to 7 business days
CPT Code	83520 x 3

*Stability refers to samples in a storage unit (i.e., refrigerator, freezer). This is not shipping stability.

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Clinical Significance	The anti-phospholipid syndrome (APS) is a disorder of recurrent vascular thrombosis associated with persistently positive anticardiolipin (aCL) or lupus anticoagulant tests. In patients with APS, anticardiolipin antibodies bind a variety of charged phospholipids, including phosphatidylethanolimine, as well as they do cardiolipin. Lupus patients also have high titers of autoantibodies to various phospholipids, including phosphatidylethanolimine. Presentations of the syndrome include thrombosis of deep veins of the legs, as well as renal, hepatic, inferior vena cava or sagittal veins. Occlusion of the arterial circulation may be manifested as stroke, ischemic retinopathy, myocardial or bowel infarction, or peripheral gangrene. Thrombosis can occur in veins or arteries of any size. Recurrent pregnancy loss also appears to be the result of thrombosis within the placental vasculature. Anti-phospholipid antibody tests are supplemental tests and should not be used alone for diagnostic purposes. Diagnosis of anti-phospholipid syndrome must be made in conjunction with other clinical indications.
Principle	This qualitative procedure uses direct ELISA (Enzyme-Linked Immunosorbent Assay) technology. Microwell plates are coated with the appropriate phospholipid. Anti-phospholipid IgG, IgM, and IgA normal and elevated controls and patient sera are applied to the plate and any anti-phospholipid antibodies are extracted from the samples by the bound antigen. Other serum components are washed away, and a secondary antibody, specific for human IgG, IgM, or IgA and labeled with HRP (horseradish peroxidase), is added. It binds only to the immobilized human antibody. The amount of labeled secondary antibody that becomes bound to the plate is then quantified by the addition of the HRP substrate, TMB 3,3'5,5' – tetramethylbenzidine). TMB is oxidized by HRP and a color change from clear to blue occurs. The saturation of the color is directly proportional to the amount of HRP bound to the support. An acidic solution is added to stop the reaction. The resulting yellow color is then read on a standard plate reader.