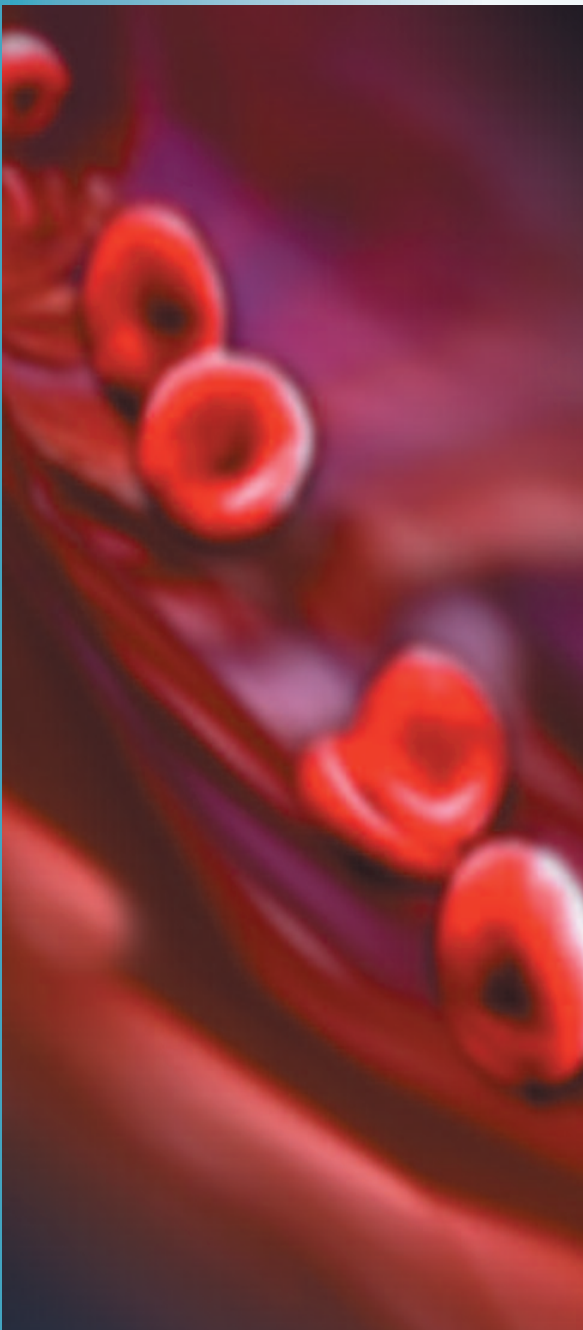


Antiphospholipid Syndrome

Comprehensive range of Enzyme Immunoassays for the investigation of Antiphospholipid syndrome.

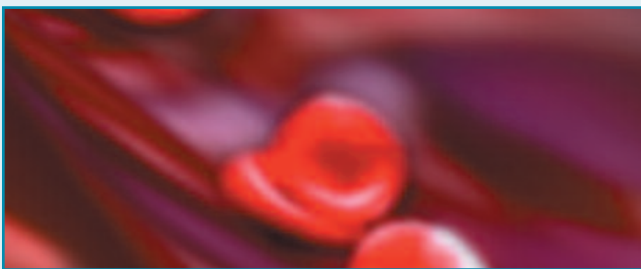


- **Common protocols for easy automation - IFA & EIA**
- **Validated protocols for DS2™ & DSX™**
- **Individual components and kits for flexible immunofluorescence testing**

ANTIPHOSPHOLIPID SYNDROME

Antiphospholipid syndrome

Antiphospholipid syndrome (APS), also known as Hughes syndrome, is an autoimmune condition associated with recurring vascular thrombosis and pregnancy morbidity.¹ APS is divided into primary APS where the condition occurs alone, and secondary APS where the condition occurs in association with other autoimmune diseases such as systemic lupus erythematosus (SLE).²



In the venous system, thrombosis may result in deep vein thrombosis (DVT) and pulmonary embolism, or stroke and ischaemic attack in the arterial system². Some patients may develop an acute small vessel ischaemia involving multiple organs resulting in the potentially life threatening condition catastrophic APS.³ Besides thrombosis and pregnancy morbidity other clinical features of APS include thrombocytopenia, *livedo reticularis*, nephropathy, neurological manifestations and heart valve disease.⁴ Patients with APS are managed by the prophylactic use of drugs, including heparin and aspirin, to reduce the risk of thrombosis.⁵

Clinical Significance

Antibodies targeting cardiolipin, $\beta 2$ glycoprotein-1 ($\beta 2$ GP-1) and phosphatidylserine are commonly found in patients with the clinical symptoms of APS.^{2,6} Specifically, antibodies to cardiolipin are found in approximately 80-90% of patients with primary APS.⁷ Evidence has demonstrated that the antibodies target a complex comprising phospholipid and a plasma binding protein, $\beta 2$ GP-1.⁸ Consequently to ensure increased specificity anti-phospholipid enzyme immunoassays (EIA) commonly include $\beta 2$ GP-1 cofactor in the coating antigen.

Diagnostic criteria

For a patient to be diagnosed with APS they must first meet one of the following clinical criteria:

- i) one or more episodes of arterial, venous, or small vessel thrombosis in any tissue or organ
- ii) pregnancy morbidity including foetal death, premature birth or spontaneous abortion⁴

Once a patient's clinical symptoms fulfil the clinical criteria, diagnosis of APS can be confirmed if one of the laboratory criteria is met.

Laboratory Criteria	
Anti-Cardiolipin Antibodies EIA	IgG or IgM in serum or plasma
Anti- $\beta 2$ Glycoprotein-1 Antibodies EIA	IgG or IgM in serum or plasma
Lupus Anticoagulant Non-EIA	Measures <i>in vitro</i> activation of the coagulation cascade in plasma

Laboratory tests should be performed on two or more occasions at least 12 weeks apart.⁴

Transient increases in antibodies to cardiolipin and $\beta 2$ GP-1 may be detected in patients with bacterial infections although these are not usually associated with thrombosis.⁹

Although not currently included in the diagnostic criteria, IgA cardiolipin and $\beta 2$ GP-1 antibodies are often detected in patients with APS¹⁰ and may be of particular use in detecting APS in certain ethnic groups.¹¹ Antibodies against other phospholipids like phosphatidylserine have been shown to be associated with reproductive failure.¹²



Standardisation

Much international collaboration has focused on identifying and overcoming issues related to inter-laboratory assay variation. To date anti-cardiolipin assays have been directly or indirectly calibrated to the Louisville (Harris) standards whilst there has been no internationally recognised standard for anti- β 2GP-1. Recently the standardisation committee of the European Forum for Antiphospholipid antibodies has supported the introduction of two monoclonal standards (HCAL for IgG and EY2C9 for IgM) that have dual functionality for both cardiolipin and β 2GP-1

(results expressed in $\mu\text{g}/\text{mL}$). Calibration against monoclonal standards ensures that consistent and reproducible results are seen across the whole calibration curve for IgG and IgM assays.^{13, 14}

Binding Site "S" range anti-cardiolipin and anti- β 2GP-1 EIAs calibrated to the internationally available monoclonal proteins have been developed in response to efforts to standardise assay testing in APS.

PROPOSED ANTIPHOSPHOLIPID TESTING PROTOCOL

A laboratory test is performed to confirm diagnosis if the patient shows one of the clinical symptoms of APS:

1. One or more clinical episodes of arterial, venous or small vessel thrombosis in any tissue or organ.
2. Pregnancy morbidity including foetal death, premature birth or spontaneous abortion.

APS EIA Laboratory Tests*

Anti-cardiolipin and Anti- β 2-Glycoprotein-1 EIA - IgG, IgA and IgM

Positive result

Negative result

But
clinical symptoms suggest APS

Positive result

Anti-Phosphatidylserine EIA - IgG, IgA and IgM

Negative result

Probable APS
- if present alongside clinical symptoms

APS not confirmed

* Laboratory tests should be performed on 2 or more occasions at least 12 weeks apart

Ordering Information



DESCRIPTION	PACK	CODE
Anti Cardiolipin IgG S EIA	96 test	MK127
Anti Cardiolipin IgA S EIA	96 test	MK128
Anti Cardiolipin IgM S EIA	96 test	MK129
Anti Cardiolipin IgGAM S Screen EIA	96 test	MK130
Anti β 2GP-1 IgG S EIA	96 test	MK140
Anti β 2GP-1 IgA S EIA	96 test	MK141
Anti β 2GP-1 IgM S EIA	96 test	MK142
Anti β 2GP-1 IgGAM S Screen EIA	96 test	MK143

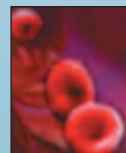
IgG and IgM S range assays are calibrated against monoclonal standards, reporting units ug/mL. Other assays are available. Please refer to website for details: www.bindingsite.co.uk

DESCRIPTION	PACK	CODE
Anti Phosphatidylserine IgG EIA	96 test	MK050
Anti Phosphatidylserine IgA EIA	96 test	MK051
Anti Phosphatidylserine IgM EIA	96 test	MK052

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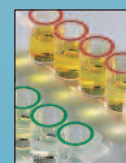
THE BINDING SITE LTD.
PO Box 11712,
Birmingham,
B14 4ZB, UK
Tel: +44 (0)121 436 1000
Fax: +44 (0)121 430 7061

info@bindingsite.co.uk
www.bindingsite.co.uk



THE BINDING SITE INC.
5889 Oberlin Drive
Suite 101, San Diego,
CA 92121, USA
Tel: 858 453 9177
Fax: 858 453 9189

Toll Free: 1 800 633 4484
info@thebindingsite.com



THE BINDING SITE GmbH
Robert-Bosch-Str. 2A
D-68723 Schwetzingen
Germany
Tel: +49 (0)6202 9262 0
Fax: +49 (0)6202 9262 222

Bestell-Fax: +49 (0)6202 9262 111
office@bindingsite.de



THE BINDING SITE
Centre Atoll
14 rue des Glairaux
BP 226
38522 Saint Egrève
France

Tel: 04.38.02.19.19
Fax: 04.38.02.19.20
info@bindingsite.fr



THE BINDING SITE
Balmes 243 4º 3ª
08006 Barcelona
Spain
Tel: 902027750
Fax: 902027752

info@bindingsite.es

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