Test Definition: PSPT
Phosphatidylserine/Prothrombin Antibody, IgG and IgM, Serum

Overview

Useful For
Preferred second-tier panel for the detection of IgG and IgM antibodies against phosphatidylserine/prothrombin complex in patients with strong suspicion of antiphospholipid syndrome (APS) who are negative for the APS criteria laboratory tests (lupus anticoagulant, IgG and IgM anticardiolipin/beta 2-glycoprotein I, and anti-beta 2-glycoprotein I antibodies)

May be useful for the evaluation of patients with prior positive lupus anticoagulant results who are on direct oral anticoagulant therapy

May be useful as a risk marker for thrombosis in antiphospholipid antibody carriers

Profile Information

<table>
<thead>
<tr>
<th>Test Id</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>PSPTG</td>
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<tr>
<td>PSPTM</td>
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Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Ordering Guidance
Cardiolipin and beta-2 glycoprotein testing are the first-tier test options for most patients. Phosphatidylserine/prothrombin antibodies are considered part of the second-tier workup.

Specimen Required
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Test Definition: PSPT
Phosphatidylserine/Prothrombin Antibody, IgG and IgM, Serum

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume
0.4 mL

Reject Due To

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<th>Condition</th>
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<td>Gross hemolysis</td>
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<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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<td>Gross icterus</td>
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Specimen Stability Information

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<th>Time</th>
<th>Special Container</th>
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Clinical & Interpretive

Clinical Information

According to the 2006 revised Sapporo classification criteria, a diagnosis of antiphospholipid syndrome (APS) is based on the presence of specific pregnancy-related morbidities, arterial or venous thrombosis in association with persistent lupus anticoagulant (LA), anticardiolipin IgG/IgM or anti-beta 2-glycoprotein I IgG/IgM antibodies. (1) Cardiolipin is an anionic phospholipid that interacts with the protein cofactor beta 2-glycoprotein I. LA is an indirect assessment for the presence of antiphospholipid antibodies, which is evident in the in vitro prolongation of phospholipid-dependent coagulation. (2) Anticardiolipin and anti-beta 2-glycoprotein I antibodies are detected in solid-phases immunoassays using beta 2-glycoprotein I-dependent cardiolipin/or beta 2-glycoprotein I alone as substrate, respectively. (2,3)

There is evidence from multiple studies to suggest that patients with APS may develop autoantibodies to other phospholipid/protein complexes, specifically phosphatidylserine/prothrombin (PS/PT). (4-9) Like beta 2-glycoprotein-dependent I cardiolipin, PS/PT is a complex composed of the anionic phospholipid phosphatidylserine and the protein cofactor prothrombin. In a systematic review, Sciascia et al demonstrated that the presence of anti-PS/PT IgG antibodies is an independent risk factor for arterial and/or venous thrombotic events, with odds ratio (OR) of 5.11 (95% CI: 4.2-6.3). (4) A multicenter study showed that IgG anti-PS/PT were more prevalent in APS patients (51%) than in those without (9%), OR 10.8, 95% CI (4.0-29.3), p < 0.0001. (5) Furthermore, a number of studies have shown clinical and laboratory evidence that PS/PT antibodies may be a useful second-line test for the evaluation of patients at-risk or suspected with suspected APS, particularly for those individuals with evidence of thrombosis or abnormal LAC testing. (6,7) While anti-PS/PT antibodies were highly prevalent and correlated with other anti-PL antibodies, IgG anti-PS/PT conferred a high risk for thrombosis (8,9) but not for pure hematologic involvement. (9) These antibodies may also be seen in patients with other autoimmune diseases such as systemic lupus erythematosus. (5,8) In individuals who test positive for antiphospholipid antibodies without clinical features of APS (carriers), the cumulative incidence rate of thrombotic events has also been reported to be significantly higher for anti-PS/PT IgG positive than
anti-PS/PT IgM positive subjects.(10)

**Reference Values**

Negative < or =30.0 U  
Borderline 30.1-40.0 U  
Positive > or =40.1 U

**Interpretation**

A positive and persistent result for anti-phosphatidylserine/prothrombin complex IgG and/or IgM antibodies may be suggestive of a diagnosis of antiphospholipid syndrome (APS) in patients with evidence of arterial, venous, or specific pregnancy-related morbidities. These antibodies may also exist prior to the occurrence APS clinical manifestations as well as in patients with other systemic autoimmune diseases such systemic lupus erythematosus.

Anti-phosphatidylserine/prothrombin complex IgG antibodies have relatively higher correlations with positive results for lupus anticoagulant than the IgM isotype as well as significant risk for APS-associated thrombotic events compared to the IgM isotype in antiphospholipid antibody carriers.

A negative result does not exclude the diagnosis of APS, as other phospholipid/protein antibodies are also associated with this disorder.

**Cautions**

A diagnosis of antiphospholipid syndrome (APS) should not be based only on the presence of anti-phosphatidylserine/prothrombin antibodies. Results must be interpreted in the appropriate clinical context.

Anti-phosphatidylserine/prothrombin complex IgM antibodies have a lower risk for APS-associated thrombotic events compared to the IgG isotype in carriers.

A negative result for anti-phosphatidylserine/prothrombin IgG and IgM antibodies does not exclude the diagnosis of APS.

Anti-phosphatidylserine/prothrombin IgG and IgM antibodies are not yet included in the classification criteria for APS.

**Clinical Reference**

Performance

Method Description

The QUANTA Lite aPS/PT assay is an enzyme-linked immunosorbent assay. Briefly, purified phosphatidylserine/prothrombin (PS/PT) complex is coated onto a 96-well plate. Calibrators, controls, and diluted patient samples are added to the wells of the plate. If present, IgG antibodies or IgM antibodies to the PSPT complex will bind during an incubation step. After a wash step, an antihuman IgG or IgM horseradish peroxidase-labelled conjugate is added. After another incubation and wash step, a peroxidase substrate solution is added, which will change color in the presence of the conjugated enzyme. Lastly, the reaction is stopped by the addition of 0.44 M sulfuric acid. The absorbance of the colored produced is proportional to the amount of IgG or IgM PS/PT antibodies in the sample. Control and patient results are calculated based on a curve generated from the kit calibrators. (Packet inserts: QUANTA Lite aPS/PT, IgG ELISA kit. INOVA Diagnostics; Rev. 2, 1/2016; QUANTA Lite aPS/PT, IgM ELISA kit. INOVA Diagnostics; Rev. 4, 09/2018)

PDF Report

No

Day(s) Performed

Wednesday

Report Available

2 to 8 days

Specimen Retention Time

14 days

Test Definition: PSPT
Phosphatidylserine/Prothrombin Antibody, IgG and IgM, Serum
Performing Laboratory Location
Rochester

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
86148 x 2

LOINC® Information

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