MAYO CLINIC LABORATORIES

Test Definition: PSPTM

PS/PT Ab, IgM, S

Overview

Useful For

Detection of IgM antibodies against phosphatidylserine/prothrombin complex in patients with strong suspicion of antiphospholipid syndrome (APS) who are negative for the APS criteria laboratory tests (l(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 (DOAC) therapy

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

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

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Collection Information: Centrifuge and aliquot serum.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Minimum Volume

0.4 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	21 days	

	Frozen	21 days	

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 (LAC), 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. LAC 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 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 (SLE).
A negative result does not exclude a diagnosis of APS, as other phospholipid or 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 IgM antibodies does not exclude the diagnosis of APS.
Anti-phosphatidylserine/prothrombin IgM antibodies are not yet included in the classification criteria for APS.

Clinical Reference

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9. Nunez-Alvarez CA, Hernandez-Molina G, Bermudez-Bermejo P, et al: Prevalence and associations of anti-phosphatidylserine/prothrombin antibodies with clinical phenotypes in patients with primary antiphospholipid syndrome: aPS/PT antibodies in primary antiphospholipid syndrome. Thromb Res. 2019 Feb;174:141-147. doi: 10.1016/j.thromres.2018.12.023
10. Tonello M, Mattia E, Favaro M, et al: IgG phosphatidylserine/prothrombin antibodies as a risk factor of thrombosis in antiphospholipid antibody carriers. Thromb Res. 2019 May;177:157-160. doi: 10.1016/j.thromres.2019.03.006

Performance

Method Description

The QUANTA Lite sPS/PT IgM assay is an enzyme-linked immunosorbent assay (ELISA). 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, IgM antibodies to the PS/PT complex will bind during an incubation step. After a wash step, an antihuman 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 IgM PSPT antibodies in the sample. Control and patient results are calculated

based on a curve generated from the kit calibrators.(Packet insert: QUANTA Lite aPS/PT, IgM ELISA kit. INOVA Diagnostics; Rev. 4, 09/2018)

PDF Report
No

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & Codes

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