MAYO CLINIC LABORATORIES

Test Definition: PSPTG

Phosphatidylserine/Prothrombin Antibody, IgG, Serum

Overview

Useful For

Detecting IgG 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

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

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK
Heat treated	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

The 2023 American College of Rheumatology/European Alliance of Associations for Rheumatology antiphospholipid syndrome (APS) classification criteria includes an entry criterion of at least one positive antiphospholipid antibody (aPL) test within 3 years of identification of an aPL-associated clinical criterion, followed by additive weighted criteria (score range 1-7 points each) clustered into 6 clinical domains (macrovascular venous thromboembolism, macrovascular arterial thrombosis, microvascular, obstetric, cardiac valve, and hematologic) and 2 laboratory domains (lupus anticoagulant functional coagulation assays, and solid-phase enzyme-linked immunosorbent assays for IgG/IgM anticardiolipin and/or IgG/IgM anti-beta 2-glycoprotein I antibodies) (1)Cardiolipin is an anionic phospholipid that interacts with the protein cofactor beta 2-glycoprotein I. Lupus anticoagulant (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 LA 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

<18 years: Not established
> or =18 years:
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 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 a diagnosis of APS, as other phospholipid and/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.

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

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

Clinical Reference

1. Barbhaiya M, Zuily S, Naden R, et al. The 2023 ACR/EULAR antiphospholipid syndrome classification criteria. Arthritis Rheumatol. 2023;75(10):1687-1702. doi:10.1002/art.42624
2. Pengo V, Bison E, Denas G, Jose SP, Zoppellaro G, Banzato A. Laboratory diagnostics of antiphospholipid syndrome. Semin Thromb Hemost. 2018;44(5):439-444. doi:10.1055/s-0037-1601331
3. Tebo AE. Laboratory evaluation of antiphospholipid syndrome: An update on autoantibody testing. Clin Lab Med. 2019;39(4):553-565. doi:10.1016/j.cll.2019.07.004
4. Sciascia S, Sanna G, Murru V, Roccatello D, Khamashta MA, Bertolaccini ML. Anti-prothrombin (aPT) and anti-phosphatidylserine/prothrombin (aPS/PT) antibodies and the risk of thrombosis in the antiphospholipid syndrome. A systematic review. Thromb Haemost. 2014;111(2):354-364. doi:10.1160/TH13-06-0509
5. Amengual O, Forastiero R, Sugiura-Ogasawara M, et al. Evaluation of phosphatidylserine-dependent antiprothrombin antibody testing for the diagnosis of antiphospholipid syndrome: results of an international multicentre study. Lupus. 2017;26(3):266-276. doi:10.1177/0961203316660203
6. Heikal NM, Jaskowski TD, Malmberg E, Lakos G, Branch DW, Tebo AE. Laboratory evaluation of anti-phospholipid syndrome: A preliminary prospective study of phosphatidylserine/prothrombin antibodies in an at-risk patient cohort. Clin Exp Immunol. 2015;180(2):218-226. doi:10.1111/cei.12573

7. Nakamura H, Oku K, Amengual O, et al. First-line, non-criterial antiphospholipid antibody testing for the diagnosis of antiphospholipid syndrome in clinical practice: A combination of anti-beta 2 -glycoprotein I domain I and anti-phosphatidylserine/prothrombin complex antibodies tests. Arthritis Care Res (Hoboken). 2018;70(4):627-634
8. Radin M, Foddai SG, Cecchi I, et al. Antiphosphatidylserine/prothrombin antibodies: An update on their association with clinical manifestations of antiphospholipid syndrome. Thromb Haemost. 2020;120(4):592-598. doi:10.1055/s-0040-1705115
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;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;177:157-160. doi:10.1016/j.thromres.2019.03.006

Performance

Method Description

The QUANTA Lite aPS/PT IgG 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 to the PS/PT complex will bind during an incubation step. After a wash step, an antihuman IgG 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 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 IgG. INOVA Diagnostics; Rev 2, 01/2016)

PDF Report

No

Day(s) Performed

Wednesday

Report Available

2 to 8 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Test Definition: PSPTG

Phosphatidylserine/Prothrombin Antibody, IgG, Serum

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

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PSPTG	PS/PT Ab, IgG, S	85359-8

Result ID	Test Result Name	Result LOINC® Value
PSPTG	PS/PT Ab, IgG, S	85359-8