Test Definition: PSPT

PS/PT Ab, IgG/IgM, S

Overview

Useful For

Second-tier evaluation of patients with suspected antiphospholipid syndrome

Evaluation of patients with a strong suspicion of antiphospholipid syndrome for whom anticardiolipin/beta 2-glycoprotein I and anti-beta 2-glycoprotein I antibody testing was negative

Evaluation of patients with evidence of a functional lupus anticoagulant

Detection of both IgM and IgG antibodies against phosphatidylserine/prothrombin

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
PSPTG	PS/PT Ab, IgG, S	Yes	Yes
PSPTM	PS/PT Ab, IgM, S	Yes	Yes

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Advisory Information

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.

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

A diagnosis of antiphospholipid syndrome (APS) is based on clinical and laboratory evaluation. The clinical manifestations associated with APS include arterial and venous thrombosis and recurrent pregnancy loss. The laboratory testing for APS focuses on assessment for autoantibodies specific for phospholipid/protein cofactor complexes. The current criteria require detection of anticardiolipin, anti-beta 2-glycoprotein I, or lupus anticoagulant (LAC) for classification of APS.

Cardiolipin is an anionic phospholipid that interacts with the protein cofactor beta 2-glycoprotein I. Anticardiolipin and anti-beta 2-glycoprotein I antibodies are detected by immunoassay using the antigen of cardiolipin/beta 2-glycoprotein I or purified beta 2-glycoprotein I, respectively. LAC is an indirect assessment for the presence of antiphospholipid antibodies, which is evident in the in vitro prolongation of phospholipid-dependent coagulation.

There is evidence to suggest that patients with APS may develop autoantibodies to other phospholipid/protein complexes, specifically phosphatidylserine/prothrombin (PS/PT). Similar to cardiolipin/beta 2-glycoprotein I, PS/PT is a complex composed of the anionic phospholipid phosphatidylserine and the protein cofactor prothrombin. A recent systematic review has demonstrated that anti-PS/PT antibodies are a significant risk factor for arterial and venous thrombotic events, with an odds ratio of 5.11 (4.2-6.3). In addition, a separate study indicated that anti-PS/PT antibodies showed the highest correlation with LAC, compared to anticardiolipin or anti-beta 2-glycoprotein I antibodies (p=0.002). Anti-PS/PT antibodies may be a useful additional marker for evaluation of patients with suspected APS, particularly for those individuals with evidence of thrombosis or abnormal LAC testing.

Reference Values

Negative < or =30.0 U

Borderline 30.1-40.0 U

Positive > or =40.1 U

Interpretation

A positive result is consistent with the presence of an antibody specific for the phosphatidylserine/prothrombin complex, and may be consistent with a diagnosis of antiphospholipid syndrome (APS) in patients with evidence of arterial or venous thrombosis or recurrent pregnancy loss.

A negative result is consistent with the absence of an antibody specific for the phosphatidylserine/prothrombin complex. However, this 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 antiphosphatidylserine/prothrombin antibodies.

A negative result for antiphosphatidylserine/prothrombin antibodies does not exclude the diagnosis of APS.

Antiphosphatidylserine/prothrombin antibodies are not yet included in the classification criteria for APS.

Clinical Reference

1. Otomo K, Atsumi T, Amenqual O, et al: Efficacy of the antiphospholipid score for the diagnosis of antiphospholipid syndrome and its predictive value for thrombotic events. Arthritis Rheum 2012;64:504-512

2. Hoxha A, Ruffatti A, Tonello M, et al: Antiphosphatidylserine/prothrombin antibodies in primary antiphospholipid syndrome. Lupus 2012;21:787-789

3. Sciascia S, Sanna G, Murru V, et al: Validation of a commercially available kit to detect anti-phosphatidylserine/prothrombin antibodies in a cohort of systemic lupus erythematosus patients. Thromb Res 2014;133:451-454

4. Sciascia S, Sanna G, Murru V, et al: 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;111:354-364

5. Heikal NM, Jaskowski TD, Malmberg E, et al: Laboratory evaluation of anti-phospholipid syndrome: A preliminary prospective study of phosphatidylserine/prothrombin antibodies in an at-risk patient cohort. Clin Exp Immunol 2015;180:218-226

Performance

Method Description

The QUANTA Lite sPS/PT 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, 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, Rev. 2 1/2016, INOVA diagnostics, San Diego, CA; QUANTA Lite aPS/PT, IgM ELISA kit, Rev. 4 9/2018, INOVA diagnostics, San Diego, CA)

PDF Report

No

Day(s) and Time(s) Test Performed

Tuesday; Evening

Analytic Time

1 day

Maximum Laboratory Time

7 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. 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 U.S. Food and Drug Administration.

CPT Code Information

86148 x 2

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PSPT	PS/PT Ab, IgG/IgM, S	In Process

Result ID	Test Result Name	Result LOINC Value
PSPTM	PS/PT Ab, IgM, S	85358-0
PSPTG	PS/PT Ab, IgG, S	85359-8