Autoimmunity

Setting the standard

EliA™ antiphospholipid syndrome serology testing:

The clinical performance of the EliA™ antiphospholipid (aPL) portfolio provides reliable test results that aid in the diagnosis of antiphospholipid syndrome (APS).[1-8]

5%

Up to 5% of the general population have aPL antibodies.[9] 20% of patients with aPL antibodies have reported deep vein thrombosis, stroke (female; <45 years old), recurrent miscarriages, teenage epilepsy (idiopathic; in teenagers), and/or lupus.[10]

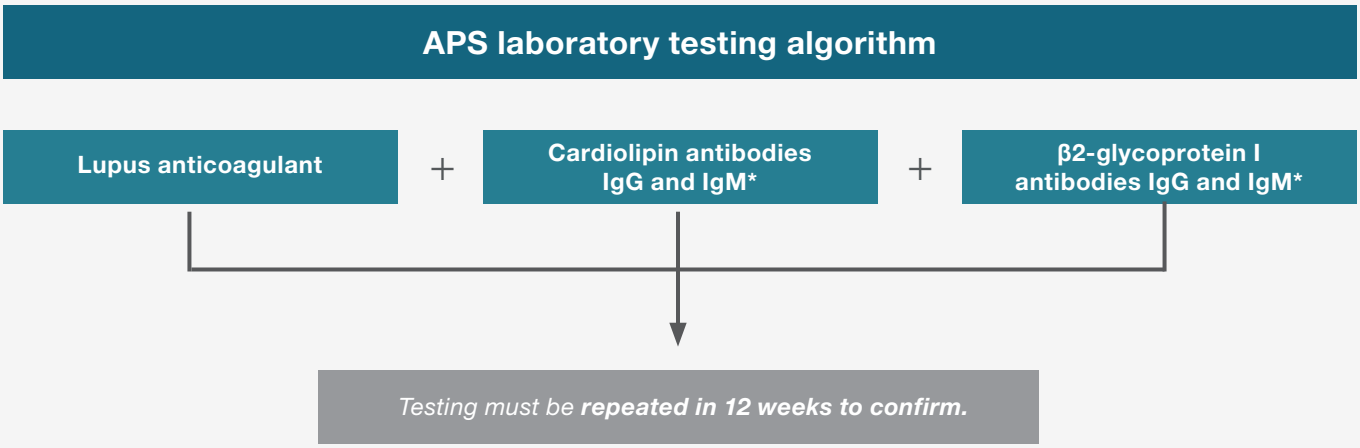
78% of patients do not receive the full panel of tests recommended upon initial suspicion of APS.[13]

APS is a systemic autoimmune disease defined by:[11,12]

- Entry criterion of at least one positive aPL antibody test within 3 years of identification of an aPL-associated clinical criterion, followed by additive weighted criteria clustered into 6 clinical domains and 2 lab domains
- Persistent positive tests for aPL antibodies

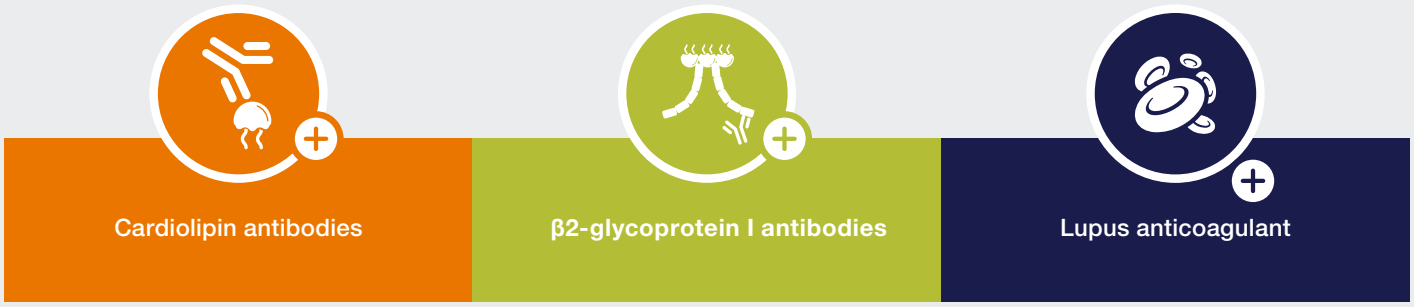
Consider an APS serology profile:

The diagnosis of APS is supported by the detection of aPL antibodies on two or more occasions at least 12 weeks apart. Currently, lupus anticoagulant, cardiolipin antibodies (IgM/IgG), and β2-glycoprotein I antibodies (IgM/IgG) are considered as part of the laboratory criteria.[14]



*If initial tests for criteria markers (including β2GPI IgG/IgM and CL IgG/IgM) are negative and a high suspicion of APS for a patient exists, β2GPI IgA and CL IgA may be considered.[15]

If all 3 antibodies are positive, there is a **98% risk for APS**[16]



APS interpretation considerations:

- Not every positive aPL test is clinically significant[17]
- Transient aPL positivity is common during infections[17]
- Clinical judgment is required[17]

Women's health considerations:

- When APS is appropriately treated, more than 70% of pregnant women will deliver live newborns[18]
- 1:5 Women are disproportionately affected by APS—the male to female ratio is 1:5[19]
- APS is typically diagnosed between the ages of 30 and 40[19]

Note: As with all diagnostic testing, any diagnosis or treatment plan must be made by the clinician based on test results, individual patient history, the clinician's knowledge of the patient, as well as their clinical judgment.

Official product name for APS disease serology testing mentioned in this document include EliA Cardiolipin IgA, EliA Cardiolipin IgG, EliA Cardiolipin IgM tests and EliA β2-Glycoprotein I IgA, EliA β2-Glycoprotein I IgG and EliA β2-Glycoprotein I IgM tests.

References

1. EliA β2-Glycoprotein I IgM Directions for Use. (2020). Phadia 250 Laboratory System. **2.** EliA β2-Glycoprotein I IgG Directions for Use. (2020). Phadia 250 Laboratory System. **3.** EliA β2-Glycoprotein I IgA Directions for Use. (2020). Phadia 250 Laboratory System. **4.** EliA Cardiolipin IgM Directions for Use. (2020). Phadia 250 Laboratory System. **5.** EliA Cardiolipin IgG Directions for Use. (2020). Phadia 250 Laboratory System. **6.** EliA Cardiolipin IgA Directions for Use. (2020). Phadia 250 Laboratory System. **7.** Villalta D, Alessio M G, Tampoia M, Re A Da, Stella S, Re M Da, et al. Accuracy of the First Fully Automated Method for Anti-Cardiolipin and anti-beta2 Glycoprotein I Antibody Detection for the Diagnosis of Antiphospholipid Syndrome. Ann N Y Acad Sci. 2009 Sep;1173:21-7. **8.** Pérez D, Martínez-Flores JA, Serrano M, Lora D, Paz-Artal E, Morales JM, et al. Evaluation of Three Fully Automated Immunoassay Systems for Detection of IgA Anti-Beta 2-glycoprotein I Antibodies. Int. Jnl. Lab. Hem. 2016 Oct;38(5):560-8. **9.** Misita CP, Moll S. Antiphospholipid antibodies. Circulation. 2005 Jul 19; 112(3):e39-44. doi: 10.1161/CIRCULATIONAHA.105.548495. PMID: 16027261. **10.** Hughes G. The Big 3. Lupus. 2018 Oct;27(1_suppl):4-7. doi: 10.1177/0961203318801681. PMID: 30452319. **11.** Barbhaiya M, Zuily S; ACR/EULAR APS Classification Criteria Collaborators. 2023 ACR/EULAR Antiphospholipid Syndrome Classification Criteria. Arthritis Rheumatol. 2023 Aug 28. doi: 10.1002/art.42624. Epub ahead of print. PMID: 37635643. **12.** Katrien M.J. Devreese, Stéphane Zuily, Pier Luigi Meroni, Role of antiphospholipid antibodies in the diagnosis of antiphospholipid syndrome, Journal of Translational Autoimmunity, Volume 4, 2021, 100134, ISSN 2589-9090, https://doi.org/10.1016/j.jtauto.2021.100134. **13.** Novak, D. Identifying potential care gaps in the diagnosis of antiphospholipid syndrome – a United States real-world data evaluation. Poster presented at CORA; March 16-18; Turin, Italy. **14.** Miyakis S, Lockshin MD, Atsumi T, Branch DW, Brey RL, Cervera R, Derksen RH, DE Groot PG, Koike T, Meroni PL, Reber G, Shoenfeld Y, Tincani A, Vlachoyiannopoulos PG, Krilis SA. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J Thromb Haemost. 2006 Feb;4(2):295-306. doi: 10.1111/j.1538-7836.2006.01753.x. PMID: 16420554. **15.** Zohoury N, Bertolaccini ML, Rodriguez-Garcia JL, Shums Z, Ateka-Barrutia O, Sorice M, Norman GL, Khamashta M. Closing the Serological Gap in the Antiphospholipid Syndrome: The Value of "Non-criteria" Antiphospholipid Antibodies. J Rheumatol. 2017 Nov;44(11):1597-1602. doi: 10.3899/jrheum.170044. Epub 2017 Sep 1. PMID: 28864642. **16.** Pengo V. Ruffatti A, Del Ross T , Tonello M. Cuffaro S, Hoxha A, Banzato A, Bison E, Denas G, Bracco A, Padayattil Jose S. Confirmation of initial antiphospholipid antibody positivity depends on the antiphospholipid antibody profile. J Throm Haemost 2013 Aug; 11(8): 1527-31. doi: 10.1111/jth. 12264. PMID 23601766. **17.** Cush J. Across the Table on Antiphospholipid Syndrome [Internet]. Medical News and Free CME Online. MedpageToday: 2017 [cited 2020Dec28]. **18.** Di Prima FA, Valenti O, Hyseni E, Giorgio E, Faraci M, Renda E, De Domenico R, Monte S. Antiphospholipid Syndrome during pregnancy: the state of the art. J Prenat Med. 2011 Apr;5(2):41-53. PMID: 22439075; PMCID: PMC3279165. **19.** Bhana, Suleman, MD. "Antiphospholipid Syndrome." American College of Rheumatology, March. 2019, www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Antiphospholipid-Syndrome

Learn more at **thermofisher.com/EliA**