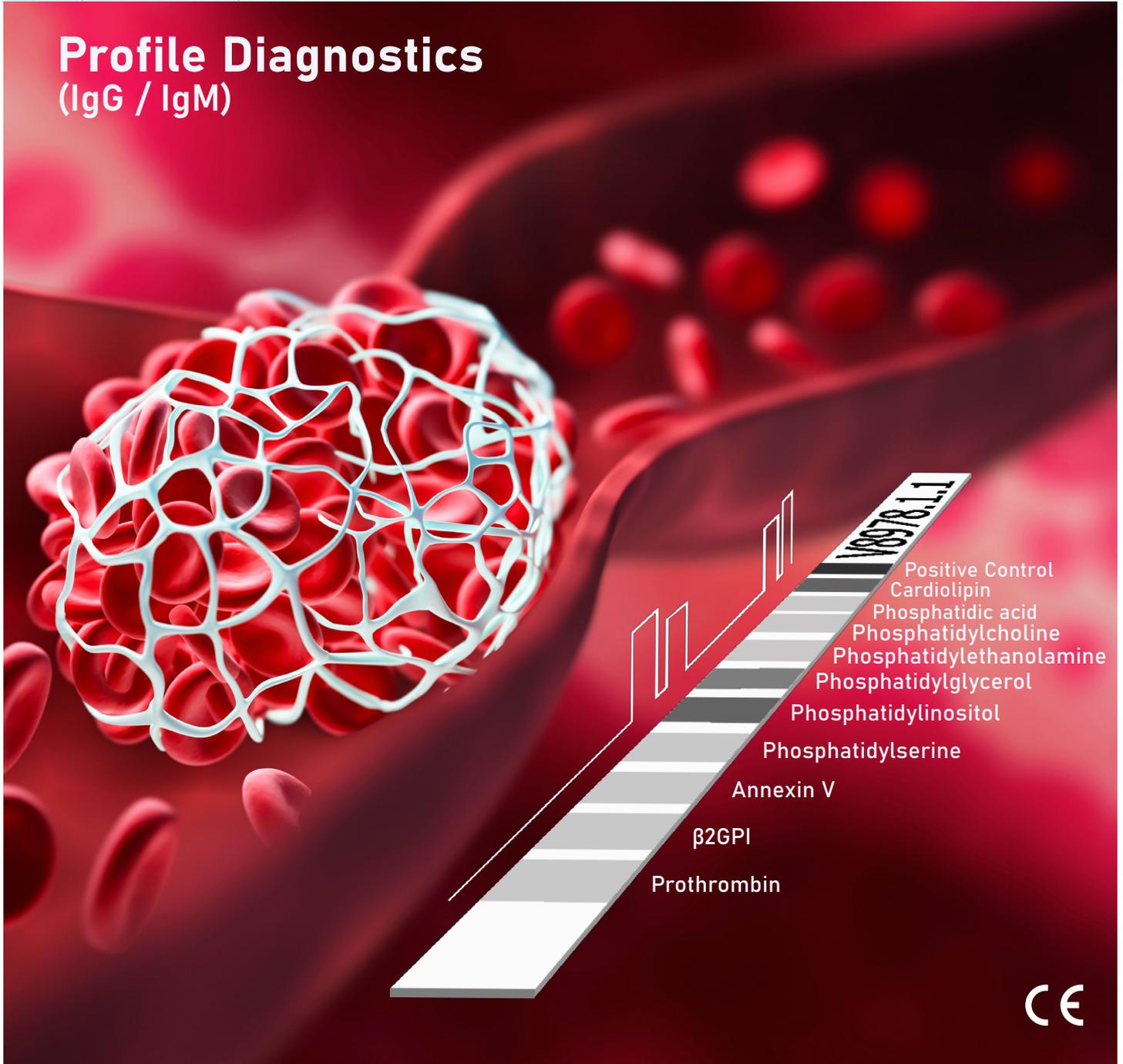


Anti-Phospholipids



LINE Immunoassay for the determination of IgG or IgM antibodies to phospholipids and serum proteins in human serum

Profile Diagnostics (IgG / IgM)



Product Highlights

- Specific detection of IgG and IgM antibodies against phospholipids (aPL)
- Serological marker for antiphospholipid syndrome (APS)
- Excellent Simultaneous detection of 10 criteria and non-criteria aPL

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Anti-Phospholipids

LINE Immunoassays for the determination of IgG or IgM antibodies to phospholipids and serum proteins in human serum

Anti-Phospholipid Syndrome

Antiphospholipid syndrome (APS) is a chronic autoimmune disorder affecting approximately 1% of the population, either as a primary condition or in association with other autoimmune diseases. It is characterized by recurrent thrombosis and/or pregnancy complications in the presence of antiphospholipid antibodies (aPL). Diagnosis relies on both clinical and laboratory criteria, with solid-phase assays detecting persistent aPL, including IgG and IgM to beta-2-glycoprotein I (β 2GPI), the cardiolipin (CL)- β 2GPI complex and the lupus anticoagulant (LA) clotting test.

Despite advancements, aPL analysis faces challenges due to their diversity and test standardization issues. Recent research indicates that specific anti- β 2GPI antibodies may distinguish between APS-related and non-related antibodies. Various profiles of aPL positivity, such as single, double, or triple positivity, help stratify risk in APS patients, with triple positivity correlating with higher clinical risk. While LA positivity is a robust predictor, medium/high IgG levels to CL and β 2GPI are more indicative than IgM or low-level antibodies.

Although aPL are pathogenic, they typically require a "second hit" to trigger APS manifestation, which can be influenced by factors like cardiovascular risks, acquired thrombotic risks, genetic predispositions, and infections. The persistent presence of aPL in asymptomatic carriers raises questions about their pathogenic potential and the timing of the triggering event.

Advanced assay techniques, including line immunoassays (LIAs), offer improved detection and association with APS phenotype compared to traditional methods like an ELISA. LIAs, along with other novel approaches show promise in enhancing APS diagnosis and risk assessment.¹²³

Diagnostic Relevance

APAS, an autoimmune disorder evident by clinical symptoms such as thrombocytopenia, arterial (venous) thrombosis, and recurrent foetal loss, as well as systemic lupus erythematosus (SLE) is characterized by the presence of autoantibodies reactive to negatively charged phospholipids. In autoimmune patients, phospholipid antibodies seem to recognize phospholipids associated with plasma protein cofactors, e.g. β 2GPI, a serum protein with a molecular weight of ca. 50 kDa, that affects platelet aggregation and coagulation. Negatively charged phospholipids such as Cardiolipin interact with the positively charged fifth domain of β 2GPI, an interaction that leads to conformational changes of the protein and the creation of new epitopes recognized by autoimmune phospholipid autoantibodies.

¹ Roggenbuck, D. et al. (2016). Antiphospholipid antibodies detected by line immunoassay differentiate among patients with antiphospholipid syndrome, with infections and asymptomatic carriers.

² Anunciación-Llunell, A. et al. (2022). Differences in Antiphospholipid Antibody Profile between Patients with Obstetric and Thrombotic Antiphospholipid Syndrome.

³ Tkachenko, O. et al. (2020). Profiling of non-criteria antiphospholipid antibodies in patients with SLE: differentiation of thrombotic SLE patients and risk of recurrence of thrombosis.

Anti-Phospholipids

LINE Immunoassays (LIA) for the diagnostic of antiphospholipid syndrome

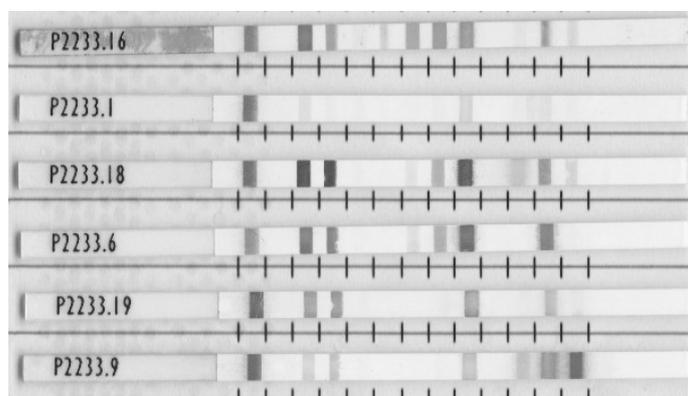
Anti-Phospholipid Assays

The LINE Immunoassay (LIA) represents a significant advancement in diagnosing antiphospholipid syndrome (APS). This innovative technique allows for the simultaneous detection of up to 10 antibodies targeting phospholipids and serum proteins in a single comprehensive assay, streamlining the evaluation process.

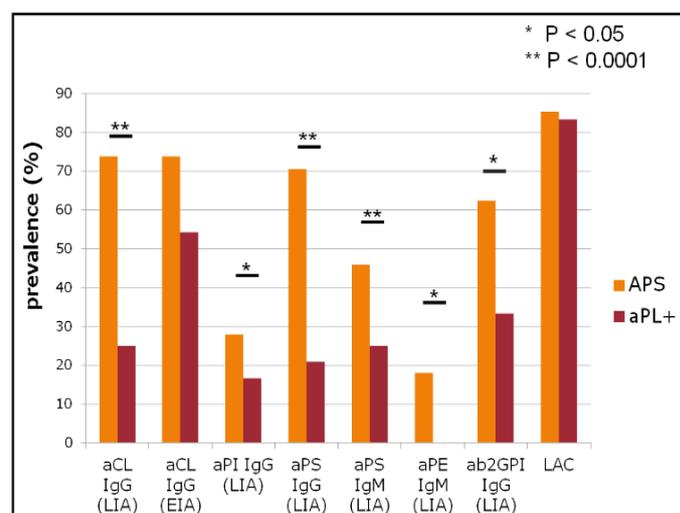
One of the key advantages of LIA is its heightened sensitivity, achieved through optimal epitope presentation on a hydrophobic membrane. This results in a stronger correlation between anti-phospholipid antibodies detected via LIA and the presence of APS, covering both general symptoms and specific complications such as recurrent miscarriages or cerebrovascular events associated with the syndrome. Additionally, LIA demonstrates reduced reactivity to transient antibodies, particularly those produced

during infectious diseases. This characteristic decreases the likelihood of false positives, ensuring greater precision in APS diagnosis and monitoring. LIA offers a cost-effective approach to APS diagnostics by simplifying the procedure and requiring fewer determinations compared to traditional ELISA methods. This improved efficiency translates into cost savings for healthcare providers and patients alike, enhancing access to APS screening and monitoring.

In summary, the LINE Immunoassay (LIA) emerges as a valuable diagnostic tool for antiphospholipid syndrome (APS), providing heightened sensitivity, specificity, and cost-effectiveness compared to conventional methods. Its ability to detect multiple antibodies in a single assay makes it indispensable for managing APS and its associated complications.



Profiles of antibodies against phospholipids and serum proteins of various APS patients in the anti-phospholipid 10 Dot.



Differentiation between APS patients (n=61, Istituto Auxologico Italiano) and asymptomatic patients with phospholipid antibodies (n=24); the LIA shows significantly higher sensitivities for APS patients compared to ELISA (EIA) (Roggenbuck et.al, CORA 2015).¹

Automated



Anti-Phospholipid Assays for

DotDiver2.0

Automated Immunoblot Analyzer

- Automated LINE / Dot immunoblot benchtop analyzer with small footprint
- User-friendly software
- Simultaneous performance of up to 24 different tests
- Ready-to-use reagents and test strips
- Automated barcode identification of test strips and cartridges
- Integrated drying of processed test strips
- Evaluation of processed test strips
- Export of results in digital file format or as print out
- LIS connectivity
- Low-maintenance, no liquid handling

Manual



Anti-Phospholipid 10 Dot

Classic version with manual processing and visual for automated evaluation through scan software (i.e. Blot GALaxy).

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Order Information



Anti-Phospholipid IgG

REF 50401

(24 x 9 Determinations)



Anti-Phospholipid IgM

REF 50411

(24 x 9 Determinations)



Anti-Phospholipid 10 Dot

REF 5012

(20 x 10 Determinations)